

Population Council Program III
HRN-A-00-99-00010

Year Five Program Report

1 July 2003–30 June 2004

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GLOSSARY

Population Council Program III (PCP3). USAID Cooperative Agreement HRN-A-00-99-00010 with the Population Council.

Activity. Sometimes also referred to as a project. Each program consists of one or more activities.

Collaborating organizations. (1) Contractors for the purchase of significant goods or services under the activity; or (2) organizations involved in the activity that do not receive any PCP3-source funds.

Contribution to results framework. The intermediate result expected from the activity, as specified in the USAID-mandated Results Framework for the PCP3.

Division. The Population Council is organized into several divisions. Program activities are carried out in three of these divisions, the Center for Biomedical Research (CBR), the International Programs Division (IPD), and the Policy Research Division (PRD). CBR conducts biomedical research, IPD conducts international programs, and PRD conducts policy research.

Implementing organization. The organization that receives USAID-source funds to undertake the activity—either the Council or a subrecipient.

Period. The expected period of the activity, beginning at the time Population Council Program funds were first spent on the activity (either under the current cooperative agreement or under an earlier cooperative agreement) and ending at the time it is expected no more PCP funds will be spent (either under the current cooperative agreement or under a subsequent cooperative agreement).

Program. One of several bodies of work funded by the PCP3; divided into activities.

Technical coordinator. The Council staff member who oversees the activity.

Results framework. An outline provided by USAID to categorize the USAID strategic objectives to which work funded by the PCP3 will contribute, and to list the intermediate results leading to the strategic objectives.

Year One. 13 August 1999–31 August 2000, the first program year of the Population Council Program III cooperative agreement.

Year Two. 1 September 2000–31 August 2001, the second program year of the Population Council Program III cooperative agreement (overlaps with Year Three because of USAID-mandated change).

Year Three. 1 July 2001–30 June 2002, the third program year of the Population Council Program III cooperative agreement (overlaps with Year Two because of USAID-mandated change).

Year Four. 1 July 2002–30 June 2003, the fourth program year of the Population Council Program III cooperative agreement.

Year Five. 1 July 2003–30 June 2004, the fifth program year of the Population Council Program III cooperative agreement.

Year Six. 1 July 2004–31 August 2005, the sixth program year of the Population Council Program III cooperative agreement (consists of 14 months).

Contraceptive Development

Program Summary

The Population Council's Contraceptive Development program conducts laboratory and clinical research to develop and register new methods of contraception for women and men. Council scientists identify new drugs and design delivery systems; undertake preclinical and clinical studies; analyze and publish findings; and submit documentation of results to regulatory authorities for permission to undertake Phase 1 trials in humans or as part of a new drug application following the completion of Phase 3 trials. The Council's International Committee for Contraception Research, a cadre of distinguished investigators, conducts the program's clinical trials.

USAID has provided major funding for the Contraceptive Development program. These funds were instrumental in developing the Council's marketed contraceptive methods: the Copper T family of intrauterine devices; Norplant® and Jadelle® implants; and Mirena®, the levonorgestrel-releasing intrauterine system. Under the Population Council Program III, USAID funds supported work on a number of new methods in the product pipeline.

Nestorone® (NES)/Ethinylestradiol (EE) Contraceptive Ring

Project #07902

Country/ies: France, Netherlands, United States

Technical Coord.: Yun-Yen Tsong

Period: Pre-Year One–June 2009

Objective: To develop a new contraceptive ring system that is under the control of the user, does not require daily intake of steroids, and avoids the impact of oral steroids on the liver; and to reduce side effects related to androgenic progestins.

Activity Description:

The contraceptive ring is particularly suitable for steroid administration. When a ring is placed in the vagina, the steroid within it slowly diffuses into the blood and tissues, thereby providing a contraceptive effect by inhibiting ovulation. Because the ring is inserted and removed by the woman herself, a minimal amount of attention by medical personnel is required, and initiation and discontinuation of ring use are under the woman's control. The contraceptive vaginal ring containing NES and EE is undergoing extensive clinical trials to facilitate its approval by regulatory agencies and, eventually, introduction into family planning programs. The ring is designed for one year of use. The results of dose-finding and use-schedule studies showed the ring releasing NES/EE at a rate of 150/15 mg per day to be the most effective dose. As to the use schedules, both the three-weeks-in/one-week-out and the 26-days-in/4-days-out schedules showed excellent bleeding control and were equally effective in the prevention of pregnancy.

Commercial relationship: QPharma, ring manufacture

Report of Year Five:

July–December 2003: Three safety studies continued. One examined the effects on estrogen-dependent hepatic markers and coagulation factors of the NES/EE 150/15-µg-per-day ring; a pharmacokinetic study compared EE serum levels reached immediately upon ring insertion, when a burst of EE is released, with EE serum levels reached daily by users of a well-accepted oral contraceptive; and a third study compared the effects on coagulation factors of EE alone released via a vaginal ring with EE administered orally.

Feasibility assessments of mass manufacturing the rings concluded. Technology transfer to QPharma continued, and manufacturing scale-up activities took place. Manufacturing trials for the original batch of ring bodies were completed. However, the supplier of the elastomer used in the manufacture of rings was bought out by a competitor, NuSil Technology. The technology was transferred to NuSil, where production was scaled up. *In vitro* testing of the NuSil product revealed differences in release rates from the original material, however, requiring reformulation. Manufacturing trials for a new batch of ring bodies began, necessitated by the switch in the source of the material used to make the ring bodies.

January–June 2004: The three safety studies concluded. A review of the available data from the three studies took place at the April 2004 ICCR meeting. The data confirmed that the effect of EE on liver proteins is similar whether the steroid is administered orally or vaginally, and showed that some of the metabolic effects of the vaginal ring are in line with those observed with third-generation oral contraceptives. The results of the three studies indicate that the NES/EE ring is safe for further development.

At QPharma, manufacturing trials continued for the new batch of ring bodies, necessitated by the change in

the source of the material used to make them; commercial production of the rings was therefore delayed. Trial batches of ring bodies were manufactured and sent to CBR, where steroid cores were inserted so that *in vitro* testing of assembled rings could take place. QPharma also commenced the steroid core manufacturing trials.

Implementing Organization(s): Saint-Antoine Hospital, Paris (CB03.107A)
Health Research Associates, LAC/USC (CB03.106A)
Netherlands Organization for Applied Scientific Research (CB02.111A)

Activity Funding: Pop Core

Contribution to Results Framework: IR 1.1

Nestorone® (NES)/Estradiol (E₂) Contraceptive Ring

Project #TBD

Country/ies: United States

Technical Coord.: Yun-Yen Tsong

Period: N/A

Objective: To develop a new contraceptive ring system that is under the control of the user, does not require daily intake of steroids, and avoids the impact of oral steroids on the liver; to reduce side effects related to androgenic progestins.

Activity Description:

The contraceptive ring is particularly suitable for steroid administration. When a ring is placed in the vagina, the steroid within it slowly diffuses into the blood and tissues, thereby providing a contraceptive effect by inhibiting ovulation. Because the ring is inserted and removed by the woman herself, a minimal amount of attention by medical personnel is required, and initiation and discontinuation of the ring are entirely under the woman's control. A contraceptive vaginal ring containing NES and ethynylestradiol (EE) has undergone extensive testing. It is hoped that this NES/EE ring will be developed for Phase 3 testing and, eventually, introduction into family planning programs. However, the use of synthetic EE may have an adverse effect on hepatic factors in women. Should current investigations prove this to be the case, EE will be replaced with natural E₂ in the ring formulation.

Final Report:

Results from the three safety studies of the NES/EE contraceptive vaginal ring indicate that the NES/EE ring is safe for further development. Therefore, the NES/E₂ ring project will not go forward.

Implementing Organization(s): Population Council

Activity Funding:

Contribution to Results Framework: IR 1.1

Nestorone® (NES) Implant

Project #07703

Country/ies: United States

Technical Coord.: Irving Sivin

Period: Pre-Year One–December 2003

Objective: To develop a single implant releasing NES that will provide contraceptive protection while avoiding the adverse effects of oral steroids on the liver and reducing side effects related to androgenic progestins.

Activity Description:

A single implant releasing the progestin NES and intended for two years of use is being developed by the Population Council. The steroid is not active orally as a result of a high rate of first-pass hepatic metabolism, a feature that makes the NES implant an ideal method for lactating women. A Phase 2 dose-finding study indicated that a dose corresponding to an *in vitro* release rate of 100 mg per day exhibited good suppression of ovulation and prevented pregnancy through 23 months. A single pregnancy occurred in the 24th month. Accordingly, the implant was redesigned to provide an *in vitro* release rate of approximately 115 mg per day. The reformulated implant was 4.5 cm long, had a smaller diameter, and contained a higher drug load. These features were expected to extend the implant's effectiveness to two full years and, with respect to pregnancy prevention, provide a margin of safety of a few months beyond two years. A Phase 2b clinical trial of the reformulated implant was initiated during Year One of the Population Council Program III. Although initial results of this trial were favorable, one pregnancy occurred during each of the first three months of 2002. The pregnancies occurred at months 18, 21, and 24 of implant use. Accordingly, the decision was made to close out the trial in the period late Year Three/early Year Four.

Final Report:

USAID funds under the PCP3 supported in-house activities associated with Protocol 263, the Phase 2b clinical study of the reformulated NES implant (described under the Activity Description). These activities included pre-clinical studies such as implant manufacturing, *in vitro* studies of implant release rates, and costs associated with clinical monitoring activities. Also included were activities involving regulatory affairs paperwork related to closing out the study, and the preparation of a manuscript for publication of the study results.

Implementing Organization(s): Population Council

Activity Funding: Pop Core

Contribution to Results Framework: IR 1.1

Nestorone® (NES), Not Method-Specific

Project #07600

Country/ies: United States

Technical Coord.: Narender Kumar

Period: Pre-Year One–Post-Agreement

Objective: To conduct synthesis and formulation of NES; radioimmunoassay of clinical blood samples; and pharmacology, metabolism, and toxicology studies required by regulatory agencies for all methods using NES.

Activity Description:

In order to carry forward the clinical studies of NES, various safety, pharmacology, and metabolism studies are required. Studies seek to generate a body of data that will meet the regulatory requirements for clinical trials of all methods releasing NES.

Report of Year Five:

A preclinical study of NES initiated in early 2003 concluded. To further characterize the metabolic pattern of NES, the *in vitro* metabolism of labeled NES was studied using rat and human liver microsomes. Study results indicated that NES has several metabolites, some common to both rat and human liver microsomes. No conjugation occurred with human liver microsomes. An absorption and excretion study in adult female rats also concluded. It showed that approximately 95 percent of the administered dose was excreted in feces and 7 percent was excreted in urine over five days. Thus, biliary excretion is the primary elimination route of NES. Pharmacological studies continued in animals to investigate the antiestrogenic effects of NES in comparison with two other progestins.

Implementing Organization(s): Population Council

Activity Funding: Pop Core

Contribution to Results Framework: IR 1.1

Jadelle® (Two-Rod Levonorgestrel Implant System)

Project #07702

Country/ies: United States

Technical Coord.: Irving Sivin

Period: Pre-Year One–Post-Agreement

Objective: To secure from the U.S. Food and Drug Administration (FDA) approval of Jadelle as a five-year method.

Activity Description:

Jadelle (formerly known as Norplant® II) is a set of two 4-cm implants that release the progestin levonorgestrel steadily over five years and at reduced rates for two to three years thereafter. The Population Council, with the support of USAID, received FDA approval in 1996 for use of this contraceptive for three years. Clinical trials have continued, and the five-year cumulative pregnancy rate is 1.1 per 100, with an average annual Pearl pregnancy rate of less than 0.2 per 100 woman years. Because the longer use-life is believed to be advantageous to women seeking long-term protection against pregnancy, the Council wishes to obtain FDA approval for five years of use.

Commercial relationship: Schering Oy, manufacturing and marketing

Report of Year Five:

The Council assisted the manufacturer in its effort to register Jadelle in Venezuela. Venezuelan regulatory authorities requested that the manufacturer provide an authenticated statement on the composition of Jadelle, which Council staff requested and obtained from the FDA. Also on behalf of the manufacturer, the Council submitted to the FDA two chemistry, manufacturing, and control supplements and, for the clinical pharmacology and biopharmaceutics commitment, a postmarketing study final report. Council staff had ongoing interaction with the FDA and the manufacturer regarding the two supplements; one was approved and the other is pending. Council staff also began preparing an annual report on Jadelle to be submitted to the FDA.

Implementing Organization(s): Population Council

Activity Funding: Pop Core

Contribution to Results Framework: IR 1.1

CDB-2914 (Progesterone Receptor Modulator)

Project #07909

Country/ies: Chile, Dominican Republic, United States
Technical Coord.: Yun-Yen Tsong
Period: July 2001–June 2003
Objective: To evaluate the effectiveness of a vaginal ring delivering CDB-2914 on a continuous basis.

Activity Description:

Data from studies conducted in Population Council laboratories indicate that the potent progesterone receptor modulator CDB-2914 can cross the vaginal mucosa in rabbits. *In vitro* tests of the molecule in a ring formulation indicate that it diffuses through the silastic of the ring. A ring is envisioned that women can use on a continuous basis.

Final Report:

USAID support under PCP3 for the vaginal ring delivering CDB-2914 included pre-clinical work (including ring manufacture and *in vitro* release studies) in support of the initial clinical trial to test this ring (Protocol 312). Protocol 312 was carried out during Year Four of the Population Council Program III to evaluate a ring releasing approximately 400 µg of the progesterone receptor modulator CDB-2914. The objectives were to determine the absorption of the molecule, the effect of CDB-2914 on ovulation, and its effect on the endometrium. Pharmacokinetic data indicate that CDB-2914 was readily absorbed into the bloodstream, reaching a plateau at serum levels of 2–3 ng/mL, as measured by radioimmunoassay. Ovulation was completely suppressed in three women, delayed in four, and was normal in five. Endometrial biopsies were taken on day 28 of ring use for all 12 subjects. Most of the subjects were in the secretory phase with endometrial maturation markedly delayed in all subjects. With the exception of two subjects, no bleeding occurred during ring use. Withdrawal bleeding occurred following a decrease in progesterone levels. These results indicate that the dose of CDB-2914 tested in this study was partially effective in preventing or delaying ovulation in a few subjects. The changes observed in the endometrium also indicate a local effect of the progesterone receptor modulator. The data suggest that an increase of 25–50 percent of the dose delivered per day will result in ovulation suppression.

Implementing Organization(s): Chilean Institute of Reproductive Medicine (ICMER) (CB02.103A)
Dominican Association for the Well-Being of the Family
(PROFAMILIA) (CB02.102A)
Population Council

Activity Funding: Pop Core

Contribution to Results Framework: IR 1.1

Androgen Implant

Project #07801

Country/ies: Chile, Germany, United States

Technical Coord.: Narender Kumar

Period: Pre-Year One–June 2004

Objective: To develop an implant releasing the synthetic androgen MENT™ to suppress spermatogenesis and replace testosterone in normal, fertile men.

Activity Description:

Suppressing spermatogenesis by blocking gonadotropin secretion is a promising approach to male contraception. MENT, a synthetic androgen, is a potent suppressor of gonadotropin secretion, which leads to a reduction of testosterone production and cessation of spermatogenesis. Prior to implant fabrication, MENT is converted to MENT acetate (MENT Ac), as the acetate form of the drug is more readily released from subdermal implants. MENT Ac is rapidly hydrolyzed into MENT *in vivo*. Because of its high potency, the effective doses are very low, making it feasible for MENT to be administered for extended periods via implants. MENT Ac implants have been developed and tested in normal and hypogonadal men and found to elicit dose-related responses.

Final Report:

During the PCP3, a multicenter dose-finding study of MENT Ac implants was concluded (Protocol 246). A total of 36 normal men were enrolled at three ICCR clinics and used one, two or four MENT Ac implants. Suppression to azoospermia occurred in nine of 11 subjects in the four-implant group compared to two of 11 subjects in the two-implant group and none of 12 subjects in the single-implant group. During treatment no serious general side effects, signs of androgen deficiency, or extrusion of implants were observed.

Efforts were undertaken subsequent to the study to reformulate the implants so that fewer implants would be required to deliver sufficient MENT to provide a contraceptive effect. In addition, as several reports from other laboratories indicated that a combination of a synthetic progestin such as levonorgestrel and an androgen may be an effective approach for male contraception, a study was planned to compare MENT alone, released from reformulated implants, with three groups of various MENT-plus-levonorgestrel dose combinations (Protocol 320). The three clinical sites were Münster, Germany, Santiago, Chile, and Los Angeles. Subjects in all groups at each of the three clinics showed suppression of testosterone. Sperm suppression was uneven, however, and there were wide inter-clinic variations. In general, subjects in the Los Angeles clinic responded best to treatment and subjects in Münster responded the least. These responses appear unrelated to the ethnicity of the study subjects. As the trial was designed to be truncated at 6 months of use if more than 30% of subjects did not achieve azoospermia (the absence of sperm in semen), the decision was taken to close out the study. Implant removal proved to be a challenge in some subjects, as the reformulated MENT implants were made with thinner tubing, in order to allow for greater drug content. For this reason, future studies of the MENT implant will utilize the original formulation of implants.

USAID support was also used during PCP3 to support the in-house costs for an investigator-initiated study by the Medical Research Council in Edinburgh, Scotland (Protocol 349). The study compares the original formulation of MENT implants in combination with Implanon® (a single, progestin-releasing implant that is on the market for female contraception), and testosterone pellets, also in combination with Implanon. A

total of 36 subjects are taking part, with 18 randomized to each treatment arm.

Implementing Organization(s): Institute of Reproductive Medicine of the University of Münster
(CB99.016A)

Harbor-UCLA Research & Education Institute (CB02.108A)

Institute of Reproductive Medicine of the University of Münster
(CB02.107A)

Chilean Institute of Reproductive Medicine (ICMER) (CB02.106A)

Population Council

Collaborating Organization(s): Dominican Association for the Well-Being of the Family (PROFAMILIA)
Great Britain Medical Research Council

Activity Funding: Pop Core

Contribution to Results Framework: IR 1.1

Androgen, Not Method-Specific

Project #12400

Country/ies: United States

Technical Coord.: Narender Kumar

Period: Pre-Year One–June 2004

Objective: To conduct synthesis and formulation of MENT™; radioimmunoassay of clinical blood samples; and pharmacology, metabolism, and toxicology studies required by regulatory agencies for all methods using MENT.

Activity Description:

In order to carry forward the clinical studies of MENT, various safety, pharmacology, and metabolism studies are required. Studies seek to generate a body of data that will meet the regulatory requirements for clinical trials of all methods releasing MENT.

Commercial relationship: Schering AG, development

Final Report:

Various toxicology, mutagenicity, and absorption, distribution, metabolism, and excretion (ADME) studies of MENT were carried out during PCP3 to establish the safety profile of this molecule. A chronic toxicology study was completed in rats and monkeys, indicating that MENT is not toxic and is safe for further development. Mutagenicity studies were completed per U.S. Food and Drug Administration guidelines. These showed no evidence of genotoxic potential on the part of MENT. *In vitro* studies to identify the liver enzymes involved in the metabolism of MENT Ac were completed. It was determined that both rat and human liver metabolize MENT Ac in a similar way. The effects of androgens on protein synthesis and degradation machinery was investigated. Results showed that androgens have an effect on the proteosome pathway in muscle, suggesting a possible mechanism for the anabolic action of androgens.

A study was carried out to evaluate the bone- and muscle-sparing potential of MENT. The study was conducted in an aged orchietomized rat model. Rats were treated with 4, 12, or 36 µg/day of MENT via mini-osmotic pumps. Prostate weights were increased above normal only in the high dose group. In contrast, all three MENT doses were equally bone sparing at the spine, hip and tibia. This suggests that low doses of MENT would support bone and muscle growth without overstimulating the prostate. Additional studies were planned to investigate if aromatization of MENT to estradiol is required for bone-sparing effects of MENT.

Also included under this category is radioimmunoassay of serum samples for MENT from the clinical trials of MENT Ac implants (Protocol 246) and MENT Ac implants in combination with progestin implants (Protocols 320 and 339).

Implementing Organization(s): Population Council

Collaborating Organization(s): University of Helsinki

Activity Funding: Pop Core

Contribution to Results Framework: IR 1.1

Microbicides Program

Program Summary

The goal of the Population Council's Microbicides program is to develop a female-controlled microbicide to prevent heterosexual transmission of HIV and other sexually transmitted pathogens. The program is a collaborative effort between the Council's Center for Biomedical Research (CBR) and International Programs Division (IPD). Scientists at CBR conduct basic research on disease transmission and test a variety of potential microbicides—both contraceptive and noncontraceptive—*in vitro* and in animal models. Compounds showing promise in the lab are tested in human trials conducted by CBR and IPD researchers. Clinical studies have focused on a number of carrageenan (a seaweed derivative) formulations—notably Carraguard® (PC-515), the Council's leading microbicide candidate. Researchers are also working on second-generation microbicides.

USAID funding has played a key role in supporting the Council's work on microbicides. This funding has been invaluable in attracting other donors (such as the Bill & Melinda Gates Foundation) to support the Microbicides program.

CBR: Reproductive Toxicology: Segment I and Segment II for Carraguard®

Part of project #08300

Country/ies: United States

Technical Coord.: Robin Maguire

Period: July 2001–December 2003

Objective: To ensure the safety of Carraguard when used by women of childbearing age.

Activity Description:

Reproductive toxicology profiles, required by the US Food and Drug Administration (FDA) for all drug products, are of particular importance for Carraguard. Because Carraguard is a noncontraceptive microbicide, it can and will be used by women who wish to conceive while protecting themselves and their sexual partners against infection by HIV and other sexually transmitted pathogens. Therefore, it is essential that use of the product has no adverse effects on either male or female fertility or on embryonic development pre- and postimplantation. Segment I reproductive toxicology studies, which are conducted in rats, will determine whether Carraguard has any effect on fertility or a teratogenic effect on early embryonic development through implantation. Segment II studies, which, as required, are conducted in both rodent (rat) and nonrodent (rabbit) species, will evaluate embryonic development through birth.

Final Report:

The Therimmune Research Corporation conducted a three-month Segment 2 reproductive toxicology study designed to provide data on the potential maternal and/or developmental toxicity of Carraguard administered vaginally during the period of organogenesis [Gestation Days (GD) 7-19] in the pregnant rabbit. The effects of both one and three daily applications of Carraguard were evaluated. Therimmune provided a final study report in June 2004.

Therimmune found that Carraguard treatment had no biologically significant effect on mortality, clinical observations, food consumption, gross pathology, gravid uterine weight, pregnancy status or fetal body weights. Administration of Carraguard three times daily resulted in subtle signs of maternal toxicity as evidenced by abortion, body weight loss during GD 7-10, higher post-implantation loss, and increased incidence of fetal malformations. While individually none of these parameters are statistically significant, the combined incidence may be attributable to both the high viscosity and the high vaginally administered volume dose and not a result of toxicity associated with the drug substance.

Therefore, under the conditions of this study, the no observable adverse effect level (NOAEL) for maternal and embryo/fetal toxicity was 1 dose of Carraguard daily. The lowest observable adverse effect level (LOAEL) was 3 doses of Carraguard daily. Carraguard did not appear to be teratogenic in the New Zealand White Rabbit, as embryo/fetal toxicity was only observed at a maternally toxic dose.

Implementing Organization(s): Population Council

Collaborating Organization(s): Therimmune Research Corporation
Covance Laboratories

Activity Funding: HIV/AIDS Core & Pop Core

Contribution to Results Framework: IR 1.3

CBR: Carraguard® and Placebo Production for Phase 3 Efficacy Trial

Part of project #08300

Country/ies: United States
Technical Coord.: Robin Maguire
Period: April 2002–June 2007
Objective: To implement Phase 3 gel production.

Activity Description:

Approximately 2 million applicators will be needed for the Phase 3 Efficacy Trial of Carraguard: 1 million each of Carraguard and placebo, which will necessitate approximately 18 production runs for each gel over a three-year period. The repeated production runs and the staggered production scheduling will necessitate the execution of more rigorous and extensive control and analytical testing. (The procedural development of the production protocol, controls, and analytical tests were completed prior to July 2001; the validation and documentation were included as part of “CBR: Phase 3 Documentation and Production Start-Up.”) A large portion of the initial Phase 3 gel production will occur prior to the onset of the clinical trials in order to assure that sufficient supplies of gel are stockpiled. Staggered production throughout the trial will allow for any production reruns that may be necessary and will also allow for increasing or decreasing production according to the actual amounts of gel used by study participants. Additional benefits of the staggered production schedule are convenience in obtaining and analyzing active and inactive ingredients; scheduling of production/filling equipment; microbiological, impurity, and acceptability control testing; and packaging and warehousing of accepted and released products. The early production runs and validation and release of study gels will ensure that study sites are well-stocked with the projected inventory.

Commercial relationship: Clean Chemical Sweden, manufacturing

Report of Year Five:

Three batches of study gel were produced in December 2003–February 2004 for the Carraguard Phase III clinical trial. Applicators filled with gel produced in December 2003 were shipped to clinical trial sites in March 2004. The remaining two batches of each gel await shipment to the clinical trial sites early in Year One.

In October 2003, it was decided to increase the amount of preservative in the Carraguard and methyl cellulose placebo formulations (see CBR (#08300): Stability Profiles for Carraguard® and Methyl Cellulose Placebo). Additional steps were added to the gel production protocol to incorporate more preservative, and ensure its complete dissolution, even distribution, and consistency. Validation of the new production protocol occurred in October - December of 2003.

In late 2003, the PIII production team coordinated with the clinical team to establish protocols for shipment and delivery of gel supplies to the trial sites. In addition, both teams instituted a system for product accountability.

Implementing Organization(s): Population Council

Activity Funding: HIV/AIDS Core & Pop Core

Contribution to Results Framework: IR 1.3

CBR: Stability Profiles for Carraguard® and Methyl Cellulose Placebo

Part of project #08300

Country/ies: United States

Technical Coord.: Robin Maguire

Period: July 2002–June 2008

Objective: To establish a five-year stability profile for Carraguard and a Phase 3 trial duration stability profile for methyl cellulose placebo.

Activity Description:

In order to optimize the appeal of Carraguard (once it is proven to be an effective microbicide and approved by the U.S. Food and Drug Administration) as an over-the-counter (OTC) product and to minimize its final pricing, a five-year stability testing will be conducted. Thus far, Carraguard has undergone two-year stability testing with very encouraging results. Results indicated no change in the physical appearance of the filled applicators or their gel contents nor any change in the formulation's pH, viscosity, or microbicidal strength when stored under an extreme range of temperatures and humidity conditions. Similar results were not found in evaluating the stability of methyl cellulose placebo, however. Under storage conditions of 40°C±2° and 75 percent±5 percent relative humidity the placebo exhibited deterioration of gel integrity, including change in physical appearance and decrease in pH and viscosity. Fortunately, a placebo need only remain stable for the duration of its use in clinical studies. Therefore stability studies will be conducted such that a five-year stability profile can be obtained for Carraguard and a stability profile can be obtained for methyl cellulose placebo that is sufficient for its use in the Phase 3 trial.

Report of Year Five:

Stability testing has begun on the three PIII production batches produced during December 2003–February 2004. At time = 3 months, all three batches of both Carraguard and methyl cellulose have passed stability testing.

Initially, stability testing was to be conducted on batches from an earlier round of gel production (September–November 2002), but samples from these batches yielded conflicting results in preservative challenge testing. Challenge testing involves exposing a product to specified microorganisms (those it is likely to encounter) to ascertain the ability of the product to resist contamination. It was decided to increase the amount of preservative in Carraguard to resolve any doubt that Carraguard was suitably protected from microbial contamination. Because the formulation had changed, further stability testing on the 2002 test samples was discontinued in September 2003. The increased amount of preservative is still well under that allowed by the European Union, Japanese, and U.S. regulatory authorities.

Implementing Organization(s): Population Council

Activity Funding: HIV/AIDS Core

Contribution to Results Framework: IR 1.3

CBR: Preclinical Studies for Second-Generation Microbicides

Part of project #08300

Country/ies: United States

Technical Coord.: Robin Maguire

Period: July 2002–June 2004

Objective: To advance an improved carrageenan-based second-generation microbicide into clinical testing.

Activity Description:

Over the last few years, Council researchers have been investigating methods of modifying carrageenan to improve its effectiveness, broaden the spectrum of its efficacy against sexually transmitted pathogens, and, ideally, increase its flexibility of use. One modification involved covalently bonding an additional chemical entity, zinc, to the structure of the same carrageenan, PDR98-15, that is used in the manufacture of Carraguard®. This has resulted in a significant improvement in formulation. The new second-generation microbicide, PC-710, has been shown to be significantly more effective in blocking HIV infection *in vitro* and herpes simplex virus type 2 (HSV-2) infection in mice than Carraguard. In addition, PC-710 has proven to be effective in protecting mice from HSV-2 infection for several hours, even when applied post-viral exposure. These attributes of PC-710—increased strength, flexibility of use, and duration of use—warrant moving it into the product development pipeline. Council researchers are proposing to expedite preclinical studies that will establish the basis necessary to achieve U.S. Food and Drug Administration (FDA) approval to begin clinical studies.

A recent award from the National Institute of Child Health and Human Development has provided funding for investigating the potential of the PC-710 formulation and other second-generation microbicides currently being developed in the laboratory. However, this funding is limited to evaluating formulations effective *in vitro* against HIV and *in vivo* against HIV and other sexually transmitted pathogens, evaluating their influence on dendritic cell function in mediating the transmission of HIV, monitoring preliminary stability, and examining the spreading and retention properties of the formulation. In order to advance PC-710 into clinical studies, other funding is needed for preclinical testing.

Final Report:

As was discovered with many other formulations, finding the optimal method for combining ingredients can be quite challenging. In Year 5, it was discovered that the method for formulating PC-710 generated an inconsistent formulation, including an inconsistent concentration of active ingredients. As a result, researchers developed a new method of formulating PC-710, which proved much simpler, as well as producing a consistent formulation. The new formulation re-entered the development pipeline via the laboratory screening and development regimen applied to all new formulations under development, and is described in activity: “CBR: Development of a Novel Microbicide Containing Two Anti-HIV Compounds” (PC-815).

Several laboratory batches of new PC-710 formulation were stored at 25C or 40C for stability testing. Viscosity, pH and zinc content were determined before incubation and every week for four weeks. In some cases zinc content was determined by sampling from the top and bottom of the formulation jar to assess homogeneity. The PC-710 formulations appeared to be stable, homogenous and consistent at 25C and 40C at 4 weeks of incubation. The PC-710 formulation performed similarly to its predecessor (the old version of PC-710) in *in vitro* HIV efficacy assays and in the HSV-2/mouse efficacy system.

PCP funding was critical in early stages of PC-710 development, allowing researchers to explore the finding that zinc bound to carrageenan produced an enhanced formulation that demonstrated efficacy when applied before and after viral challenge in the HSV-2/mouse model. PC-710 also appeared to provide more protection from HIV-1 *in vitro* than did Carraguard. As stated above, the stability of the initial PC-710 formulation was not optimal, prompting researchers to develop an improved formulation, which appears to be stable and effective. Development will continue on PC-710 via other funding sources.

Implementing Organization(s): Population Council

Activity Funding: HIV/AIDS Core

Contribution to Results Framework: IR 1.3

CBR: Development of a Novel Microbicide Containing Two Anti-HIV Compounds

Part of project #08300

Country/ies: United States
Technical Coord.: Robin Maguire
Period: July 2003–June 2014
Objective: To assess the suitability of PC-815, a novel combination formulation containing Carraguard® and a non-nucleoside reverse transcriptase inhibitor (NNRTI), for use as a safe, stable, and effective microbicide.

Activity Description:

Medivir Corporation has recently transferred ownership to the Population Council of an anti-HIV drug (NNRTI-815) for use as a potential microbicide. The compound is a non-nucleoside reverse transcriptase inhibitor with high specificity not only for HIV-1 but also HIV-2 and poor bioavailability when administered orally—an attractive property for a microbicide, as it suggests that if placed in the vagina the compound would not be systemically absorbed (and if absorbed in small amounts, cause no systemic adverse events). The Microbicides program has combined NNRTI-815 with Carraguard into a formulation called PC-815.

PC-815 has a “jump-start” on development as Medivir Corporation has already conducted extensive toxicology and pharmacokinetic testing on NNRTI-815. Preliminary experiments at the Population Council have shown that Carraguard does not disrupt the antiviral activity of the new compound and in fact increases the stability of NNRTI-815. Results from preliminary *in vitro* experiments indicate that NNRTI-815 offers protection from infection by HIV-1 and HIV-2 at concentrations significantly lower than PDR98-15 (the active ingredient in Carraguard). When the two compounds are combined in PC-815, an additive protective effect is observed.

Future research and analysis will focus on testing PC-815 for safety, toxicology, and pharmacokinetics via the vaginal route of administration. In addition, longer-term stability tests will be initiated as well as validation of production methodology. Efficacy will be evaluated in both *in vitro* and *in vivo* assays.

Report of Year Five:

The Phillips laboratory began developing a combination formulation containing MIV-150 and carrageenan, called PC-815, in July 2003 with funding from the Population Council Program III (PCP3), USAID cooperative agreement HRN-A-00-99-00010. PC-815 was shown to be stable for one month, to have an additive effect against HIV free virus *in vitro*, and to be nontoxic to cells at proposed doses. Based on these highly favorable results, it was decided to pursue development of a novel combination microbicide containing the two compounds.

In Year 5, the laboratory developed a screening and development regimen designed to systematize the development of new formulations and make the best use of resources. Consequently, the assays and systems that were previously reported for use in evaluating PC-815 have changed somewhat. Work on the cell-trafficking system in mice that was to employ stained macrophages was not done; however, this system may be added to the screening regimen at later stages pending further laboratory assessments. The *in vivo* mouse system that was to employ lactate dehydrogenase-elevating virus–infected macrophages was discontinued, as it was found to entail more work with less consistent results than other systems currently used in the laboratory.

One of the biggest challenges in formulation development is finding the optimal way of putting the ingredients together. Because MIV-150 is not soluble in water (and carrageenan is a water-based), researchers began investigating ethanol as a possible solvent in a solution formulation, and also making a suspension of MIV-150 and carrageenan. Per the new screening regimen, differently formulized gels, as well as varying combinations of MIV-150 and carrageenan were compared in three-month stability assessments; in HIV-1 and HIV-2 *in vitro* effectiveness assays in the presence or absence of seminal fluid; and in the *in vivo* efficacy HSV-2/mouse system. Thus far, the formulation that employs ethanol appears to be the most consistently stable, effective and safe. The optimal concentration of MIV-150 in carrageenan is soon to be determined.

Implementing Organization(s): Population Council

Collaborating Organization(s): Chiron Corporation
Medivir Corporation

Activity Funding: HIV/AIDS Core

Contribution to Results Framework: IR 1.3

CBR: Blocking DC–Virus Spread with Carrageenan-Based Agents

Part of project #08300

Country/ies: United States

Technical Coord.: Melissa Pope

Period: July 2003–June 2004

Objective: To determine whether carrageenan-based agents can block dendritic cell (DC)-driven immunodeficiency virus transmission *in vitro* and *in vivo*.

Activity Description:

Employing established *in vitro* assays, researchers at the Center for Biomedical Research (CBR) began to evaluate whether carrageenan-based agents block virus capture by DCs as well as whether these agents impede the transmission of virus from DCs to T cells. Recent data had confirmed that the capture of simian immunodeficiency virus by DCs could be efficiently blocked by carrageenan and modified carrageenan without affecting DC viability or membrane phenotype and our *in vitro* assays confirmed and expanded upon this finding. Studies conducted assessed the DC-to-T-cell spread when blocking with Carrageenan and Zn-Carrageenan. Results from these studies provided necessary data to support the *in vivo* studies.

In vivo studies to explore the ability of carrageenans to prevent vaginal infection of rhesus macaques with infectious simian/human immunodeficiency virus experienced an unexpected delay due to animal acquisition and personnel change difficulties. However, preliminary baseline data is being gathered and the *in vivo* studies will continue employing funds from other sources. The plan, slated to start in 2005, is to compare Carrageenan to Zn-Carrageenan utilizing viral load and immune responses assays as a gauge post-virus challenge. All necessary approvals and protocols are in place.

Final Report:

The *in vitro* studies analyzing carrageenan DC-virus biology were finalized within the project year and a manuscript is currently being prepared for submission in 2005. Our assays employed the use of Carrageenan and Zn-Carrageenan (which was the most promising modified Carrageenan compound at the time) as blocking agents in the virus-DC-T cell milieu. Results demonstrated that while both compounds can substantially block the ability of DCs to capture the virus, neither compound had any effect on documented DC biology. Carrageenan and Zn-Carrageenan had no effect on immature and mature DC viability, phenotype, endocytic ability, or antigen presenting capability. For these *in vitro* assays, virus concentrations used were routinely substantially greater than those that would be encountered in a natural setting, therefore our *in vitro* observations suggest that even in the presence of large amounts of virus, Carrageenans are able to impede the DC-virus interactions necessary for virus to bind and be internalized by immature and mature DCs. This is of importance, since in a human microbicide setting, it is crucial that a product exhibit microbicidal efficiency while maintaining the integrity of the immune system at mucosal tissues. Furthermore, these results have allowed for the progression of our focus to move to the new aims proposed in the new USAID agreement involving the *in vitro* characterization of PC-815 in the DC setting.

The *in vivo* arm of the studies planned for this funding period were somewhat delayed but have begun. Difficulties encountered by a personnel change and an unexpected surge in demand for the animals needed to conduct the study precipitated the delay. All animals needed were purchased and baseline data acquisition has begun. The *in vivo* Carrageenan studies evaluating Carrageenan and Zn-Carrageenan for their ability to prevent vaginal transmission of SHIV162P are scheduled to begin in 2005. These studies will continue as originally outlined; however, funds from non-USAID sources will be used to complete

these studies. The importance of this study cannot be overlooked and the results of this research will parallel well with the proposed research outlined in the new USAID agreement. Some of the animals from this study are later slated to be used as control groups for the new USAID agreement. Concurrent with these studies, a Pilot Study granted by Tulane National Primate Research Center is currently establishing the HSV vaginal infection model in macaques that will be necessary in the new USAID agreement. Our most recent research on *in vitro* HSV-2-macaque DC biology demonstrated that Indian and Chinese Rhesus macaque DCs exhibit comparable biology and susceptibility to HSV-2 infection. The data from these *in vitro* experiments is being readied in a manuscript for submission in 2004. These data lend support for the successful establishment of the HSV-2 vaginal infection model needed for the continuing macaque studies supported by the new USAID agreement.

Implementing Organization(s): Population Council

Collaborating Organization(s): Tulane National Primate Research Center

Activity Funding: HIV/AIDS Core

Contribution to Results Framework: IR 1.3

CBR: Implementation of the Phase 3 Efficacy Trial of Carraguard®

Part of project #08300

Country/ies: South Africa
Technical Coord.: Stephanie Skoler
Period: September 2002–June 2008
Objective: To determine the efficacy and long term safety of Carraguard®.

Activity Description:

A Phase 3 efficacy trial of Carraguard being implemented at three sites in South Africa began in the first quarter of 2004. The main objective of the trial is to determine whether use of Carraguard protects women from HIV infection. Work on educational materials, (see “IPD: Preparation and Scale-Up for Phase 3 Efficacy Trial of Carraguard”) will continue through the end of the agreement.

As in the Phase 2 trials in South Africa and Thailand, female volunteers are recruited from family planning and general health clinics. However, the recruitment network has been broadened to include a wide range of women in the cohort (e.g., different age groups and high- and low-frequency gel users). Each study site has developed its own detailed recruitment plans. Eligible women are HIV-negative at screening, sexually active, and not pregnant or planning to become pregnant for the duration of the trial. Participants at each study site are randomized to one of two study arms (Carraguard gel and condoms and Methyl-cellulose gel and condoms). Women are instructed to use the gel together with condoms. Approximately 6,270 women will be enrolled and will participate for up to two years. The entire cohort will be enrolled over eighteen months with total duration of the trial approximately three years. Women are asked to insert the study gel into the vagina prior to every act of vaginal intercourse, but not to use it orally or rectally. All women are asked to return to the clinic regularly for pelvic exams, STI testing and treatment for curable STIs, HIV and safer-sex counseling, interviews about compliance, and to receive more study supplies. Applicators may be tested to help determine gel usage.

The Population Council is responsible for overall coordination of the trial. The trial is implemented at MEDUNSA, UCT and the MRC. The Council carries out data management functions and safety adjudication, ensures that ethical and regulatory needs are met and that proper monitoring is in place; conducts trainings when applicable; facilitates communication between staff and reports to donors and other microbicide stakeholders. Last, the Council is responsible for providing funding and overseeing the administration of the trial sites.

Report of Year Five:

Ongoing debate within the microbicide field about optimal study design prompted further revisions in the protocol, including streamlining the study focus to one main efficacy endpoint, namely HIV infection; modifying the statistical methods used; reducing the study duration; and increasing the sample size. To ensure high-quality results, Lancet/BARC replaced MEDUNSA as the central laboratory and the contract research organization Clindev was hired to conduct regular monitoring. The Medicines Control Council (the regulatory body of South Africa) and the ethics committees of UCT, MEDUNSA, and the Population Council approved the protocol. Case record forms were formatted for the DataFax data management system and translated into all pertinent languages. A dedicated server was established at Population Council headquarters in New York to run DataFax, and the study sites were connected to it. New York data management staff were hired and trained. Standard operating procedures were finalized. A custom-made barcode system to manage gel accountability, shipping, dispensation, and return was implemented at the

sites. A test was developed that can determine whether applicators have been inserted into the vagina, and a validation study of the test was conducted at MEDUNSA. The MRC joined the team, renovated their clinic site, began hiring staff and purchasing supplies, applied for ethics approval, learned the protocol, researched the community and translated study materials into Zulu. Onsite training for the study was conducted at UCT and MEDUNSA and approximately 400 participants were enrolled! An amendment reducing the burden on the site laboratories and adding the MRC site was submitted to all ethics committees and the MCC. The PC, UCT and MEDUNSA ethics committees granted approval.

Implementing Organization(s): Medical University of Southern Africa (CB04.103A)

University of Cape Town (CB04.101A)

Medical University of Southern Africa (CB03.103A)

University of Cape Town (CB03.101A)

Population Council

Collaborating Organization(s): Clindev

Lancet/BARC

Activity Funding: HIV/AIDS Core

Contribution to Results Framework: IR 1.3

IPD: Phase 1 Safety Study of Carraguard® (PC-515) Among HIV-Positive Women and Men

Project #05603

Country/ies: South Africa

Technical Coord.: Barbara Friedland, Heidi Jones

Period: January 2000–June 2005

Objective: To examine the safety and acceptability of Carraguard when used by HIV-positive women and men.

Activity Description:

This study, originally to be conducted only among HIV-positive women, will now examine the safety and acceptability of Carraguard when used by HIV-positive women and men in Durban, South Africa. It will be the first study in which men are asked to apply Carraguard gel directly to the penis. In addition, researchers will examine genital shedding in women through analysis of cervical-vaginal lavage samples. The study is being conducted in South Africa for several reasons. First, the high prevalence of HIV in South Africa allows for easy recruitment of adequate numbers of HIV-positive participants. Second, many potential users of microbicides in South Africa are likely to be HIV-positive without knowing their HIV status. Last, it is likely that South Africa would be one of the first places microbicides would be launched once approved. IPD staff are collaborating with Gita Ramjee of the Medical Research Council (MRC) in KwaZulu-Natal, who has an extensive research infrastructure that will greatly facilitate project implementation. The protocol includes three cohorts (20 sexually abstinent women, 20 sexually abstinent men, and 20 sexually active women and their seroconcordant male partners). Each cohort will be divided into three study groups (Carraguard, placebo, and no study product). Researchers will assess mucosal safety, vaginal flora, and genital HIV shedding in women; penile safety in men; self-reported symptoms in women and men; and acceptability and use dynamics in women, men, and couples. The study is larger than initially anticipated because of the inclusion of men and sexually active women and the no-product arm in all cohorts.

Report of Year Five:

Data collection was completed on August 19, 2003. A total of 60 participants were enrolled: 20 sexually abstinent women; 20 sexually abstinent men; and 20 sexually active women. A total of 188 potential participants were screened: 98 sexually abstinent women; 45 sexually abstinent men; and 45 sexually active women. Of the 60 participants who enrolled, one withdrew early and one was lost to follow-up at the end of the study; there were no serious adverse events. Data entry was completed in December 2003 and the primary activity during Year V was data cleaning. Due to the departure of the Johannesburg-based data manager at the end of December, the data management process was moved to New York. Data cleaning, a task that involves cleaning 31 databases and resolving all queries that arose during that process, began in early 2004. A preliminary (blinded) analysis of safety and acceptability data was presented at Microbicides 2004 in London (March 2004). A close-out visit was conducted in May 2004 near the end of the data cleaning process to resolve the outstanding queries, account for all study product, and ensure that the regulatory documentation was in order. Data cleaning is nearly complete and we anticipate beginning the data analysis process early September. Testing of CVLs and genital swabs is ongoing at the Centers for Disease Control and Prevention (CDC) in Atlanta and we anticipate having the data from this component of the study by December 2004.

Implementing Organization(s): South Africa Medical Research Council (I01.27A)
Population Council

Collaborating Organization(s): US Centers for Disease Control and Prevention

Activity Funding: HIV/AIDS Core & Pop Core

Contribution to Results Framework: IR 1.3

IPD: Preparation and Scale-Up for Phase 3 Efficacy Trial of Carraguard®

Project #05604

Country/ies: South Africa

Technical Coord.: Barbara Friedland

Period: July 2001–September 2004

Objective: To increase the capacity at existing Phase 2 trial sites in South Africa, develop informed consent and educational materials, and establish community advisory groups (CAGs) for a Phase 3 Carraguard trial.

Activity Description:

A Phase 3 trial of Carraguard will be conducted at existing Phase 2 sites in South Africa—MEDUNSA and UCT—and at the Medical Research Council. Beginning in July 2001 and until the Phase 3 trial begins in March 2004, project staff will work to increase the capacity at the existing study sites in terms of personnel, space, and other resources. An integral part of preparing for the Phase 3 trial involves determining how best to obtain informed consent from study participants and how to educate the communities from which they come. Phase 2 trial informed consent procedures will be reviewed and evaluated prior to designing materials for Phase 3. A video will be developed, and the study information booklet designed for the Phase 2 trial will be adapted for Phase 3. To educate the community, local consultations among stakeholders (government officials, activists, and advocates) will be held in South Africa prior to beginning Phase 3. In addition, CAGs will be established at each of the trial sites to serve as a bridge between the community and the research team.

Beginning in Year Four, for administrative reasons, Population Council in-house costs for this activity were moved under the activity “IPD: Implementation of the Phase 3 Efficacy Trial of Carraguard.” Items remaining budgeted under this activity were the subawards to trial sites, contracts to the producers of the informed consent video and booklet, and payments to consultants and translators for informed consent materials.

Report of Year Five:

The Setshaba Research Centre in Soshanguve (MEDUNSA site) and the Empilisweni Wellness Centre in Gugulethu (UCT site) were both completed in Year V and both sites spent much of Year V gearing up to start the trial, which began at MEDUNSA in March 2004 and at UCT in April 2004. A third site in Isipingo, run by the Medical Research Council in Durban, was added in November 2004.

It was decided that a national consultation was unnecessary, at this point, as microbicides research has become familiar in the country and there is an existing microbicides research collaboration, headed by the Medical Research Council (MRC). Instead, the study teams at UCT and MEDUNSA worked in their local communities to create awareness about the trial. The MRC team conducted a stake-holder assessment and are currently evaluating the most appropriate way to involve the community at the Isipingo site. The local community advisory groups at UCT and MEDUNSA, which had been established in Year IV, met regularly about the plans for the trial, and were actively involved in the development of informed consent materials, including the video and study booklet.

Upon receipt of IRB/ethics committee approval from the Population Council, UCT and MEDUNSA, the video was completed in English, Tswana and Xhosa in December 2003. The video was subsequently translated into Zulu for the more recently-added Durban/Isipingo site, in February 2004. The study booklet,

also approved by ethics committees/IRBs at UCT, MEDUNSA and the Population Council, was pre-tested in Soshanguve (MEDUNSA site) and Gugulethu (UCT site) in October and November of 2003. Based on results of testing, the booklets were revised and printed in early 2004. The booklet for the MRC site in Isipingo (Durban) has been translated into Zulu; however, it will not be completed until Year VI pending MRC ethics approval and pre-testing of the Zulu translation.

Each site has also developed additional recruitment materials, including posters and brochures. UCT's materials were approved by the Population Council IRB and the UCT ethics committee in early 2004. These materials were subsequently printed. At MEDUNSA, there was a delay in getting approval for recruitment materials (posters and brochures); therefore, printing of these materials will not occur until August 2004. The Durban site has developed a brochure which is currently under review by the MRC's ethics committee.

Implementing Organization(s): Medical University of Southern Africa (I01.85A)
University of Cape Town (I01.81A)
Population Council

Collaborating Organization(s): US Centers for Disease Control and Prevention

Activity Funding: HIV/AIDS Core & Pop Core

Contribution to Results Framework: IR 1.3

IPD: Implementation of the Phase 3 Efficacy Trial of Carraguard®

Project #05607

Country/ies: South Africa
Technical Coord.: Barbara Friedland
Period: July 2002–August 2005
Objective: To determine the efficacy and long term safety of Carraguard®.

Activity Description:

The management of this activity was transferred from the International Programs Division (IPD) to the Center for Biomedical Research (CBR) during Year Four of the Population Council Program III (see CBR: “Implementation of the Phase 3 Efficacy Trial of Carraguard®”). IPD staff, however, continued to be involved in the implementation of the Phase 3 trial, including developing the study protocol and case record forms (CRFs) and carrying out the overall planning for the trial. This activity also includes IPD’s continued involvement in scale-up activities, including renovations at the study sites and development of educational materials (see “IPD: Preparation and Scale-Up for Phase 3 Efficacy Trial of Carraguard®”). IPD continues to be involved in developing and testing informed consent forms and educational materials. In an effort to adhere to the highest ethical standards, the informed consent forms and the process of obtaining informed consent, which includes use of a study booklet and a video, will be evaluated before and during the Phase 3 trial.

Report of Year Five:

The revised informed consent booklet was printed in English, Setswana, and Xhosa in early 2004. In addition, the University of Cape Town (UCT) and the Medical University of Southern Africa (MEDUNSA) study sites developed site-specific materials, including posters, pamphlets, and other materials for advertising in the communities and recruiting participants. Approval was received from the ethical review board for all of the materials, and final production of materials was completed at the UCT site; printing of the MEDUNSA materials will occur in August 2004. As the third trial site at the Medical Research Council (MRC) in Durban came on board in November 2003, materials production for that site has lagged behind. While the booklet has been translated into Zulu, it has not yet been printed, as the testing of the Zulu translation is pending MRC Ethics Committee approval.

The informed consent video was completed in February 2003. An oral presentation on the development of the Carraguard Phase 3 video was given at Microbicides 2004 in March 2004.

Due to delays in the starting of the trial, the informed consent evaluation has not yet begun. The MEDUNSA site began recruiting in March and the UCT team began in April, using the video and the study booklet. However, due to some changes to the informed consent standard operating procedure (SOP), including the addition of a group informed consent process before the individual one-on-one meeting with study staff, there will be a refresher training on the informed consent process at MEDUNSA and UCT at the end of June/beginning of July. Once the sites implement the new SOP and have had experience with the procedures for at least one month, we will begin the evaluation process. In addition, the Durban site will only begin recruitment in September 2004 and we will not be able to start the informed consent evaluation until at least one month after they have begun screening participants.

Implementing Organization(s): Population Council

Activity Funding: HIV/AIDS Core

Contribution to Results Framework: IR 1.3

New Technologies and Strategies for RTI Interventions

Program Summary

In many developing-country settings limited access to screening programs for reproductive tract infections (RTIs) and low use of these services in areas where they are available result in large numbers of women living with undiagnosed RTIs. Reliance on syndromic management of RTIs for women who do present at clinics further compounds the problem, as asymptomatic women often leave clinics undiagnosed and untreated. Two technologies could help to increase the number of women screened and accurately diagnosed and treated in resource-poor settings: self-sampling methods (women insert vaginal swabs or tampons themselves to be used for RTI diagnosis) and rapid diagnostic tests (rapid point-of-service tests, which provide same-day test results and can be used at home or at the clinic). Enabling women to take their own samples at home could increase the use of screening services, as both going to the clinic and undergoing a pelvic exam can serve as disincentives to seeking care, while giving women the opportunity to use rapid diagnostic tests at home could provide incentive for women to be screened for RTIs, in part by decreasing the waiting period for test results. Introducing rapid diagnostic tests in clinics could increase the sensitivity and specificity of screening procedures and help decrease providers' dependence on less-accurate syndromic management of RTIs. Council researchers are conducting studies of these technologies in Brazil and South Africa.

Council researchers also recognize that designing effective RTI interventions and introducing new sexually transmitted infection prevention technologies require an accurate understanding of sensitive sexual behaviors. Face-to-face interviews with women do not always yield precise data regarding these behaviors. Investigators have found that audio computer-assisted self-interviewing (audio-CASI) can increase the accuracy of reports of sexual behavior in some contexts. IPD researchers are collaborating with Barbara Mensch of the Policy Research Division to incorporate audio-CASI into a home sampling and rapid testing study in Brazil.

USAID funding provides critical support for these studies.

Reproductive Tract Infection Sampling Study

Project #05605

Country/ies: South Africa

Technical Coord.: Heidi Jones

Period: September 2001–March 2004

Objective: To assess self-sampling procedures (tampons and vaginal swabs) for reproductive tract infections (RTIs) in a clinic setting and to determine the prevalence of human papillomavirus (HPV) subtypes to inform the Phase 3 Carraguard® Efficacy Trial.

Activity Description:

A study will be conducted in Gugulethu, South Africa, to assess the performance, acceptability, and feasibility of new methods of collecting samples for RTI testing that may be more convenient and less invasive than standard sampling carried out during a speculum-aided pelvic examination. Recently developed sampling techniques include tampons and vaginal swabs that can be used by women themselves and do not require a pelvic exam. However, these new techniques have not yet been adequately tested in developing-country settings. In this study, researchers will compare the performance of the new sampling methods to that of the “gold-standard” clinician-obtained samples. The study will also allow measurement of the prevalence of various subtypes of HPV in Gugulethu. HPV will be one of the study endpoints in the Phase 3 trial of Carraguard, however, no data are currently available on HPV prevalence in the South African trial communities.

Final Report:

In Year Five, an oral presentation on the main study findings and one on the Human Papillomavirus (HPV) findings were presented at the International Society of Sexually Transmitted Diseases Research (ISSTD) Congress in Ottawa, Canada in July 2003. Additionally, a poster presentation on syndromic management was presented at ISSTD. In March 2004, two poster presentations, one on acceptability and one on the main study findings, were presented at the Microbicides 2004 Conference in London. Coding of qualitative transcripts was completed using Atlas-ti software. Additionally, brown bag presentations were given at the Population Council’s New York, Washington, D.C. and Johannesburg offices for internal dissemination of study results. Manuscript preparation to peer-reviewed journals is ongoing.

In this study, 450 women were recruited from a community health center in Gugulethu, South Africa from January to July 2002, of whom 150 women came in with reproductive tract infection complaints and 300 came for other reasons, such as family planning or maternal & child health. Women from both groups were randomized to receive either a tampon or two swabs. All women took their own vaginal specimen using either the tampon or swabs, as well as underwent a pelvic exam in which a clinician took swabs. Results from the laboratory diagnosis of gonorrhea, chlamydia, trichomoniasis, human papillomavirus, yeasts, and bacterial vaginosis using the self-obtained specimens were compared to results using the same laboratory diagnostics on clinician-obtained samples.

The prevalence of HPV was high, with 36% of the women positive for a high-risk type of HPV (using the Digene Hybrid Capture II test). The prevalence for chlamydia was 11%, gonorrhea 7%, trichomoniasis 11%, bacterial vaginosis (both symptomatic and asymptomatic combined) 62% and yeasts 28%.

Concordance was high between the self-samples and the clinician-obtained samples for gonorrhea, chlamydia, yeasts and bacterial vaginosis, ranging from 93-96 percent concordance with a kappa ranging

from 0.78 to 0.86. However, self-sampled specimens did not compare favorably with clinician-obtained specimens for the diagnosis of trichomoniasis and HPV, most likely due to the way these specimens were processed. Both self-sampling methods were found to be feasible, and as acceptable as speculum examination. Younger women tended to prefer self-sampling to the pelvic exam.

The results demonstrated that the self-sampled specimens performed favorably against the gold standard with the exception of two infections—trichomoniasis and HPV—and should be considered viable alternatives for collecting specimens in future studies. Using self-sampling methods may help decrease barriers to RTI screening for younger women who tended to prefer self-sampling over a pelvic exam. However, if self-sampling is to be used for trichomoniasis, diagnostic testing of the specimen using culture in Diamonds Medium cannot be recommended, a NAATS test should be used. If self-sampling for HPV is to be used, the use of a tampon in phosphate buffered saline cannot be recommended. A swab should be used and placed in HPV-specific transport medium.

Implementing Organization(s): University of Cape Town (I01.81A)
Population Council

Collaborating Organization(s): Medical University of Southern Africa

Activity Funding: HIV/AIDS Core & Pop Core

Contribution to Results Framework: IR 1.3

Home Sampling and Rapid Testing for Reproductive Tract Infections

Project #05608

Country/ies: Brazil, South Africa

Technical Coord.: Heidi Jones

Period: July 2002–August 2005

Objective: To assess the performance, feasibility, and acceptability of self-sampling by women in developing countries in their own homes; and to field-test new rapid diagnostic tests for reproductive tract infections (RTIs) in clinic and home settings.

Activity Description:

In many countries women do not have access to adequate health services for the diagnosis and treatment of RTIs. Even when health services are available, diagnosis of RTIs typically requires a clinician to take swabs during speculum-aided pelvic exams, which are invasive and often pose a serious disincentive for seeking care. Home-based self-sampling and rapid testing may significantly help reach underserved populations that need improved diagnosis and treatment, particularly those in whom the prevalence of asymptomatic RTIs is high. Indirectly, self-sampling and rapid testing would also contribute to reducing HIV transmission in these populations. The proposed activity is a follow-up to a study conducted in collaboration with the University of Cape Town. In that study, the performance, feasibility, and acceptability of clinic-based self-sampling, using swabs and tampons, was determined by comparing them with “gold-standard” clinician sampling during a speculum-aided pelvic exam (see IPD: Reproductive Tract Infection Sampling Study). In this study, the performance, feasibility, and acceptability of self-sampling by women at home will be determined in South Africa and Brazil. In addition, new rapid diagnostic tests for RTIs will be field-tested in both clinic and home settings.

Report of Year Five:

During Year Five of the Population Council Program III, data collection began for the RTI home-sampling studies in Gugulethu, South Africa, and São Paulo, Brazil.

The Brazil site received ethical approval from the Population Council’s Institutional Review Board (IRB) on June 18, 2003, from the collaborating institution’s ethics committee on August 27, 2003 and the Brazilian National Ethics Committee on November 11, 2003. The field team underwent training from November 17–21, 2003. Additionally, refresher training continued intermittently through March 2004. Rapid trichomonas tests were held by Brazilian customs in January and February and finally released in late March 2004, causing a delay in the start of the project. Additionally, the second shipment of rapid gonorrhea and chlamydia test were held by Brazilian customs from mid-July to mid-August and finally released the week of August 16, causing a hiatus in enrollment of new participants.

Laboratory personnel underwent training for use of automated Roche Cobas Amplicor technology for gonorrhea and chlamydia PCR in March 2004 when procedures for PCR diagnosis of trichomonas were also finalized. Standard Operating Procedures (SOPs) and Case Report Forms (CRFs) were finalized by March 2004 in both English and Portuguese. Recruitment and enrollment began on April 19, 2004. A site initiation and monitoring visit was completed one week after recruitment activities were initiated. Data collection is running smoothly and according to protocol, per the first monitoring and site initiation visit. As of August 13, 2004, 313 out of 816 women (41%) were enrolled. All enrolled women are being followed up at 1–2 months to discuss acceptability and use of services. Recruitment and enrollment are ongoing. Data entry screens were developed in June 2004, and the approximately first 250 participants’

forms have been single-entered. Data entry will continue to occur on a rolling basis. A poster presentation on the rapid tests and home-based study design was presented by the local PI at the 6th Brazilian Epidemiology Conference in Recife in June 2004.

The South African site received ethical approval from the Population Council IRB on April 30, 2003 and from the University of Cape Town's (UCT) Ethics Committee on June 2, 2003. An amendment to the protocol with minor revisions was approved by the Population Council IRB on August 19 and by the UCT Ethics Committee on September 19, 2003. Initial staff training occurred from July 13–19, 2003, with additional follow-up training prior to study initiation. Finalization of CRFs and SOPs occurred by September 2003. CRFs were translated into Xhosa and back-translated into English.

Recruitment and enrollment began on September 26, 2003 and was completed on March 12, 2004, after 626 women had been enrolled. As of August 13, 2004, 563 out of 626 women (90%) have completed their 6-week follow-up visit, 53 (8%) have attempted to be found and are considered lost-to-follow-up, with 10 outstanding participants to be sought. In South Africa, 30 qualitative in-depth interviews (IDIs) are being used to supplement information on acceptability of home-based screening and partner notification strategies. Data collection of IDIs began on March 12, 2004, and is ongoing. Additional qualitative training for the field collector occurred in May 2004. As of June 21, 5 IDIs were completed. Data entry screens for quantitative data collection were created by UCT staff in September 2003 who are overseeing the data entry process. Data entry and cleaning is ongoing.

Implementing Organization(s): Centro de Estudos Augusto Leopoldo Ayrosa Galvao Research Center (CEALAG) (I03.42A)
University of Cape Town (I03.31A)
Population Council

Collaborating Organization(s): International Antiviral Therapy Evaluation Center
Gynuity

Activity Funding: HIV/AIDS Core

Contribution to Results Framework: IR 1.3

Audio Computer-Assisted Self-Interviewing (Audio-CASI) to Assess Reporting of Sensitive Behaviors

Project #05609

Country/ies: Brazil
Technical Coord.: Barbara Mensch, Heidi Jones
Period: May 2003–August 2005
Objective: To assess the feasibility and acceptability of audio-CASI in a clinic setting in Brazil as compared with face-to-face interviewing; to determine whether audio-CASI produces significantly higher levels of reporting of sensitive behaviors; and to evaluate whether audio-CASI is significantly better able to predict sexually transmitted infections (STIs) than face-to-face interviewing (if adequate statistical power permits).

Activity Description:

Understanding the relationship between sexual behavior and the prevalence of STIs and HIV is imperative to designing effective interventions that attempt to maximize prevention and minimize reinfection. If risky sexual practices and partnering are under-reported in face-to-face interviews, or if condom use is exaggerated—because it is perceived to be a positive social norm within the clinic setting—the ability to predict STI infection/reinfection from behavior will be hindered. This study provides an opportunity to evaluate the reporting of risky sexual behaviors in relation to biological markers of infection.

Researchers will investigate whether audio-CASI results in more accurate reporting of sexual behavior, thereby allowing them to more accurately determine the relationship between behavior and STI prevalence. 816 women will be randomized at enrollment to either face-to-face interviews or audio-CASI on risky sexual behaviors. At the follow-up visit six weeks after home-based or clinic-based STI screening all women will have audio-CASI for their second interview, regardless of whether they had a face-to-face interview or audio-CASI at enrollment. Comparing these two interview methods at baseline, over time, and in relation to infection with STIs will provide valuable information on sexual behavior and influence future STI/HIV intervention studies.

This activity is a collaboration between IPD and PRD staff.

Report of Year Five:

Originally, this study of audio-CASI was to be conducted as part of the Phase 3 effectiveness trial of Carraguard®. However, because the start of the Carraguard trial was delayed and will continue way past the end of the Population Council Program III, researchers decided it would be more feasible to study audio-CASI as part of the Brazil home sampling study described in “Home Sampling and Rapid Testing for Reproductive Tract Infections,” which is currently in data collection. As such, this audio-CASI study was included in the protocol for the Brazil home sampling study. The study received ethical approval from the Population Council IRB on June 18, 2003, from the collaborating institution's ethics committee on August 27, 2003 and the Brazilian National Ethics Committee on November 11, 2003.

Women ages 18-40 participating in the Brazil home sampling study are being randomly assigned to either a face-to-face interview or audio-CASI at enrollment for baseline reports of sexual behavior. All of the participants are scheduled for a return visit six weeks after enrollment, where all participants undergo an audio-CASI interview about sexual behavior using the same set of questions from the enrollment interview. Rates of reporting of sensitive behaviors will be compared between the two types of

interviewing techniques at enrollment, consistency of reporting of sensitive behaviors will be measured between responses from enrollment and six week visits, and reporting from both audio-CASI and face-to-face interviews will be compared with STI laboratory results.

Population Council staff in New York, as well as staff at the clinic in Brazil with previous training in Visual Basic and Access programming, developed the audio-CASI program from November 2003 to February 2004. A portion of the program was tested for ease of use and design in November during the team training (November 17–21, 2003). The final program for the enrollment questionnaire was pilot tested from February 2–6, 2004 by a total of 13 women, 2 study staff and 11 women from the clinic. Staff at the study clinic implemented small modifications after the pilot test. The 6-week audio-CASI questionnaire was programmed and prepared for use in the field entirely by clinic staff in Brazil. The 6-week program was designed in May and pilot tested in June 2004.

Recruitment for the study began on April 19th and is estimated to continue through October, 2004, with the 6-week follow-up continuing through January 2005. SOPs and CRFs, including the audio-CASI script, were finalized by March 2004 in both English and Portuguese. A site initiation and monitoring visit was completed one week after recruitment activities were initiated. Data collection is running smoothly and according to protocol, per the first monitoring and site initiation visit, as well as an external audit. As of August 13, 2004, 336 out of 816 women (41%) were enrolled. The study will run slightly longer than originally anticipated, as enrollment was stopped for five weeks, while the second shipment of rapid gonorrhea and chlamydia tests were held by customs. Finally, a poster presentation on the ACASI study design was presented by the local PI at the 6th Brazilian Epidemiology Conference in Recife in June 2004.

Implementing Organization(s): Centro de Estudos Augusto Leopoldo Ayrosa Galvao Research Center
(CEALAG) (I03.42A)
Population Council

Activity Funding: HIV/AIDS Core

Contribution to Results Framework: IR 2.1

Expanding Contraceptive Choice

Program Summary

The Population Council's Expanding Contraceptive Choice (ECC) project worked to improve the reproductive health of women and men in developing countries by expanding their contraceptive choices and their options for preventing sexually transmitted infections (STIs), including HIV infection. The project aimed to increase the availability, accessibility, and use of safe, effective, and acceptable contraceptive and dual-protection technologies (methods that prevent both pregnancy and STIs); and it sought to (re)introduce these technologies in ways that were programmatically feasible/sustainable and were consistent with individuals' reproductive health goals. ECC staff worked with women's advocacy and health groups at community, regional, and national levels to increase individuals' informed choices within both health care and alternative service delivery systems. The program was guided by WHO's Contraceptive Strategic Assessment Framework—a three-stage strategy for contraceptive introduction designed to help policymakers and health professionals address the complex issues surrounding the introduction of contraceptive methods, including client preferences, service delivery system capabilities, provider competence, and sustainability.

USAID supported the ECC project through Year Three of the Population Council Program III, and only ongoing projects persisted into the following year. Projects in Senegal and Brazil were completed during Year Four, and one project in Ethiopia and one project in Zambia continue into Year Five.

Three other ongoing projects which are supported by missions—one in Zambia and two in Brazil—have been moved to the Mission-Funded Initiatives program. The project "From Pilot Interventions to Regional Programs: Expanding Contraceptive Choice and Improving Quality of Care in the Copperbelt" was begun under the ECC program under the title "Expanding Contraceptive Choice Demonstration Project in the Copperbelt Province of Zambia: Scaling Up." The two Brazil projects, "Improving the Quality of STI/HIV/AIDS Prevention in the Brazil/Bolivia Border Region of Corumbá/Puerto Suárez" and "Targeting Truck Drivers for STI/HIV/AIDS Prevention, Testing, and Treatment in Foz do Iguaçu (Paraná State) and Uruguaiana (Rio Grande do Sul State)," also begun under the ECC program, can similarly be found under the Mission-Funded Initiatives program.

Expanding Access to Coital-Dependent Methods and Dual Protection Within Youth-Centered Sexual and Reproductive Health Care Facilities

Part of project #03200

Country/ies: Ethiopia

Technical Coord.: John Skibiak

Period: December 2000–August 2003

Objective: To increase the use of family planning methods among young people by improving access to technologies that address their unique needs and concerns.

Activity Description:

The 1997 Ethiopia Reproductive Health Needs Assessment found that despite access to modern contraception many young people continue to engage in unprotected sex. Some young women said they felt uncomfortable taking pills or injections on a regular basis when the frequency of their sexual activity was so sporadic. While providers stock some barrier methods, these methods represent only a small percentage of the method mix in Ethiopia.

This study, implemented by the Family Guidance Association of Ethiopia (FGAE) with technical assistance and financial support from the Expanding Contraceptive Choice project, was designed to test the hypothesis that giving young people greater access to contraceptive methods that reflect the distinctive nature of their sexual behavior would increase their use of those methods and of family planning in general, resulting in fewer unplanned pregnancies and greater use of modern family planning methods. To test the hypothesis, FGAE adopted a quasi-experimental research design, drawing the experimental and control groups from its national network of eight youth centers.

At the experimental sites, access was expanded to coital-dependent methods, including methods already available in nongovernmental organization clinics (e.g., male condoms and foaming tablets) and newer technologies (e.g., female condoms and emergency contraception [EC]). The study explores whether the introduction/reintroduction of these methods will strengthen the quality of youth-centered services and expand contraceptive choice by assuring adequate contraceptive stocks, increasing knowledge of family planning, offering dual protection, and removing barriers that impede access to all methods. Results will provide FGAE and other youth-centered service providers with the knowledge, skills, and strategies required to respond more effectively to the needs of young people, to improve the quality of reproductive health services, and to more smoothly introduce new contraceptive methods into the Ethiopian family planning method mix.

Final Report:

This study was designed to test the hypothesis that greater access to contraceptive methods that reflect the distinctive nature of young people's sexual behavior will increase their use of those methods of family planning in general. For reasons related to data collection and methodology, the hypothesis was never conclusively proven; nonetheless a number of important lessons emerged from this study.

One major finding is that the effectiveness of interventions would be better measured longitudinally within individual youth centers, because of significant differences among these centers in Ethiopia. While the study was designed to compare centers cross-sectionally, data analysis was frustrated by the degree and magnitude of variations among centers. While comparisons between control and project sites as a whole did not produce conclusive results, the impact of specific changes—not all of which were directly related to

the project interventions—could be clearly ascertained within individual centers. The study produced a number of interesting findings regarding the feasibility of providing coital-dependent methods to adolescents through youth clinics in Ethiopia. The most notable of these are outlined below.

Repackaging various methods into a single youth-friendly “brand” significantly increased demand. The desirability of repackaged products was most clearly demonstrated in the case of male condoms (MCs), where the product’s popularity quickly led to unanticipated stock-outs and distribution bottlenecks.

Product availability was directly correlated with utilization. Utilization of the methods increased when repackaged supplies were available, and dropped when they were exhausted. This finding reinforces the need to ensure the continuity of contraceptive supplies, especially those targeted specifically toward youth.

Provider attitudes toward distribution also influenced utilization. While availability was a central factor in determining usage, provider attitudes and approaches to distributing supplies also exercised a significant influence over acceptance rates. Some staff at youth centers “hoarded” the popular repackaged MCs in order to conserve supplies, which ultimately reduced the total number of users. Conversely, demand for foaming tablets remained low despite adequate stocks, largely because providers were not enthusiastic about their potential appeal to adolescents. These findings suggest the need to develop uniform service delivery strategies that reflect the special concerns of adolescents, especially in regard to ECPs.

Costs of repackaging supplies, especially ECPs, are unsustainable. Despite the increased demand for and utilization of repackaged methods, especially condoms and ECPs, it was ultimately found that the monetary and logistical costs associated with repackaging were prohibitive for scaling-up. This finding highlights the utility of introducing a dedicated ECP product into Ethiopia.

In addition to these findings, which were directly related to the interventions introduced under this project, several external factors, such as fluctuations in numbers of PSPs and the launch of new activities not related to this project, also exerted notable impact on project outcomes, making comparisons between control and intervention sites less meaningful than longitudinal examinations of individual clinics.

In recognition of the contributions of this project, the Ethiopian Federal Ministry of Health requested assistance from the Population Council to develop a new project to scale-up the results of this study. With funding from the Hewlett and Concept Foundations, this new project focuses on mainstreaming ECPs in the public sector. With the participation of FGAE and other local partners, a dedicated in-service EC training curriculum was drafted and reviewed by key stakeholders. Ethiopia’s drug regulatory board is processing the registration of a dedicated ECP and has approved the importation of 40,000 units of product for use by the study. Finally, efforts are underway to incorporate EC into the pre-service training curriculum of Ethiopia’s three principal medical schools.

Implementing Organization(s): Family Guidance Association of Ethiopia (I00.106A)

Collaborating Organization(s): Doctors Without Borders International
DKT Ethiopia

Activity Funding: Special Initiatives Core

Contribution to Results Framework: IR 1.2

Study of Impact After the Introduction of Norplant® and Depo-Provera® in Zambia: Phase Two

Project #03253

Country/ies: Zambia

Technical Coord.: Saumya RamaRao

Period: September 2000–January 2004

Objective: To provide information on contraceptive use patterns and dynamics after the introduction of Norplant.

Activity Description:

The Lusaka Impact Study is being implemented through the Population Council's Quality of Care Impact project and received funding and technical assistance from the Expanding Contraceptive Choice project. The purpose of the study is to assess whether continuation of contraceptive use will be increased and unintended pregnancies reduced with greater choice of methods. To test this hypothesis, the study made use of the pilot introduction of Norplant and the reintroduction of Depo-Provera within Zambia's family planning program. Two groups of clinics in which these contraceptives were added to the existing method mix were compared to a control group of clinics with an unchanged method mix. In one group of experimental clinics, both Norplant and Depo-Provera were added to the method mix; in the second only Depo-Provera was added. Eight public-sector clinics in Lusaka city participated in the study; two in each of the experimental groups and four in the control group.

Under Phase One of this project (May 1998–September 1999; funded under the previous Population Council Program cooperative agreement CCP-A-00-94-00013) a client-flow analysis and a situation analysis were conducted in all eight clinics, a panel of 3,203 family planning users was recruited and interviewed, and 2,200 women from the panel were interviewed during a three-month follow-up. Two reports were prepared based on the client-flow analysis and results from the baseline panel and three-month follow-up interviews. In addition, an in-country dissemination meeting for Ministry of Health and USAID Mission stakeholders was held in July 2000.

Phase Two of the study consisted of a final round of data collection. Between January and May 2001 both a situation analysis and a follow-up interview with panel respondents were conducted. The situation analysis measured changes in service quality in the eight clinics since the baseline measure. The follow-up interview was done at a cohort age of approximately 24 months. (Note: The original proposal was for follow-up interviews at cohort ages 3, 15–17, and 27–29 months; however, given the high rate of loss to follow-up at the three-month interview [32 percent] and lack of resources, the design was modified for only one follow-up interview at 24 months.)

Final Report:

The Population Council Program III provided support for the second phase of the Lusaka Impact Study. The intervention involved the addition of new contraceptive methods, Norplant and Depo-Provera (DMPA), effective provider training, and adequate contraceptive supplies and equipment. The study examined the effect of the intervention on quality of care, provider's knowledge and attitude, and client behavior.

The study consisted of 8 public sector clinics in Lusaka, Zambia which were classified into 3 levels. In addition to program methods (combined and progestin-only pills, male and female condoms, foam, Noristerat, IUD, NFP, LAM, and emergency contraceptives), level A offered DMPA and Norplant®; level

B offered DMPA, and level C offered no additional methods. The baseline data collection began in 1998 and the follow-up occurred between January and May of 2001. A total number of 3,203 clients from all the clinics were recruited at the baseline and 1,469 were re-interviewed at the follow-up.

Results indicate that the intervention had some effect on expanding contraceptive choice. Family planning guidelines were used by all providers at clinic levels A and B, suggesting that they are especially useful to answer questions, solve problems and clarify counseling issues where new methods have been introduced into the method mix. Some providers in level C reported providing referrals for Norplant or offering it themselves, which can be due to staff turnovers and transfers leading to diffusion. However, this did not translate into higher levels of knowledge about the additional methods. Training of providers in levels A and B did not result in higher levels of knowledge about added methods when compared to providers in level C sites, suggesting that the addition of more methods may overwhelm rather than strengthen the service delivery system. The results from the provider interviews also suggest that the majority of providers, regardless of clinic level, counsel clients to use condoms to prevent RTI/STIs and provide HIV/AIDS information to family planning users.

Only one third of clients interviewed at baseline were followed limiting the conclusions that can be drawn about the impact of the intervention on clients' contraceptive knowledge and behavior. Respondents at levels A and B sites, from either the follow-up cohort or exit interviews, did not have significantly greater knowledge about contraceptive methods, particularly those that were added to the method mix (Norplant and Depo-Provera), than clients at level C sites. The introduction of methods at clinic levels A and B seemed to be associated with an increasing percentage of women not wanting their last pregnancy and a decrease in the percentage of women wanting their pregnancy later. Although there appeared to be an effect on clients' attitudes towards reproductive intentions and desire to space, there was no evidence of change in clients' behaviors towards contraceptive use. A complete method mix was frequently unavailable, which presumably influenced clients' continuation rates as well as their ability to freely choose or switch between methods. There were instances of stockouts; further, field reports indicated that the supply of Norplant to level A facilities was not always continuous. The highest level of contraceptive use is among respondents who visited facilities with the narrowest range of contraceptive methods, contrary to our expectations. Further, it appears that Depo-Provera has substituted Noristerat as an injectable contraceptive, though the level of injectable use is similar across all levels. We were not able to see any demonstrable increase in contraceptive continuation among respondents in level A, which could be related to the fact that only 5% of users chose Norplant at the baseline.

This mix of findings should guide implementers to identify these areas of weakness and further strengthen basic and refresher training, ensure adequate supplies and equipment, and improve other mechanisms that had been put in place in the levels A and B clinics.

A copy of the final report detailing the points listed above and the overall outcomes of the Lusaka Impact Study was submitted to USAID in June 2004.

Implementing Organization(s): Central Bureau of Statistics, Lusaka, Zambia (I00.83A)
Population Council

Activity Funding: Field Support & Pop Core

Contribution to Results Framework: IR 1.2

Core-Funded Initiatives

Program Summary

Core-funded initiatives are Population Council activities that are not part of any other program supported by the Population Council Program III (PCP3) but have results and objectives that match those of the PCP3 results framework and have been found worthy of core support. Support comes from either general USAID Office of Population core funds or from a USAID Population Office special initiative committee.

“Assessing the Impact of Improved Quality of Care on Women’s Ability to Reduce Unintended Childbearing” (Impact Studies) seeks to document the feasibility of improving quality of care in family planning programs and to assess the impact of improved quality of care on women’s ability to reduce unplanned and unwanted childbearing in a healthful manner. The Population Council initiated the program in 1995 in response to the call for client-centered reproductive health services issued at the 1994 International Conference on Population and Development. Field studies in four countries—Pakistan, the Philippines, Senegal, and Zambia—were launched between 1997 and 1999. Interventions being tested in these countries aim to improve client–provider interactions, increase contraceptive choice, and facilitate other improvements in quality of care. While studies show promising results in local settings, empirical analysis of the interrelationships among interventions, quality-of-care improvements, and individual behavior must be completed in each country. Interventions must be compared and similarities/differences in experiences and outcomes documented. Such an analysis will be useful to programs undertaking improvements in quality of care.

USAID provided necessary support for this ongoing program during Year Three, and this support assisted the program during Years Three and Four. (USAID did not fund the study in Pakistan; research in that country is funded by other donors.)

Studies in Family Planning, a peer-reviewed international quarterly published by the Population Council since 1963, is the foremost journal in the field to provide an evidence-based approach to reproductive health programs and policies in developing countries.

USAID provided funding in Year Five to help defray a loss of support from UNFPA, whose severe funding shortfalls forced it to cut back drastically on its support to NGOs. USAID’s funding helped to sustain *Studies* during 2003 at the level of excellence that the field has come to rely on.

The INTACT Network (the International Network to Analyze, Communicate and Transform the Campaign Against FGM/FGC/FC) addresses the limitations on research on female genital cutting through a network of researchers and research-minded activists. It contributes to the quality and productivity of research and to strengthening links among researchers and between researchers and those who can use the information they generate.

During Year Five the USAID FGC Special Initiative Committee redirected funds to the INTACT Network that had been allocated during Year Four to an activity of the Adolescents program.

Studies in Family Planning

Project #02800

Country/ies: United States

Technical Coord.: Julie Reich

Period: July 2003–December 2003

Objective: To provide funds for the publication of two issues of *Studies in Family Planning*.

Activity Description:

Studies in Family Planning, a peer-reviewed international quarterly published by the Population Council since 1963, is the foremost journal in the field to provide an evidence-based approach to reproductive health programs and policies in developing countries. In addition to country- and program-specific reports, *Studies* publishes review articles and concept pieces that are on the cutting edge of research. Each issue also contains a data section with findings for individual countries from the Demographic and Health Surveys, signed book reviews, and, periodically, a scholarly commentary about a topical issue.

Studies covers all aspects of family planning and reproductive health, including a broad range of emerging topics such as adolescent reproductive and social behavior, maternal mortality and morbidity, and the impact of HIV/AIDS on sexual behavior. *Studies*' roster of authors includes leading authorities in such fields as demography, sociology, anthropology, and health sciences. The journal's readership consists of policymakers, research scholars, program managers, and health-care professionals in developed and developing countries.

As of the end of volume 33, *Studies* has a circulation of 5,500, 68 percent of which is distributed free-of-charge to institutions and individuals in developing countries. The journal is also available electronically in a word-searchable format to subscribers through the Population Council's Web site. Each issue is posted online simultaneously with publication of the print edition. Subscribers have access to complete issues from 1998 on.

Final Report:

In 2003, two issues of *Studies in Family Planning*, vol. 34 no. 3 (September) and vol. 34 no. 4 (December), were published with funding from USAID. The monies helped to fund editing, production, and free distribution of copies to institutions and individuals in the developing world.

These issues can be accessed online at www.blackwellpublishing.com/sfp.

Implementing Organization(s): Population Council

Activity Funding: Pop Core

Contribution to Results Framework: IR 2.1

The INTACT Network for FGM/C Research and Change

Project #06500

Country/ies: Egypt

Technical Coord.: Barbara Ibrahim

Period: August 2003–March 2005

Objective: To promote and disseminate evidence-based research and to actively engage donors, local actors, government, and civil society organizations in a dialogue around applying collective learning to accelerate positive social change.

Activity Description:

Through the initiative of the Population Council, the Conference to Advance Research on Female Genital Cutting (FGC) took place at the Bellagio Study and Conference Center 29 April–3 May 2002. Conference participants reviewed the status of FGC research, identified important gaps, and proposed research priorities. An important objective of the conference was to develop a network of researchers, program managers, and other relevant individuals and institutions to enhance communication and use of research results on FGC.

In the weeks following the conference, an Internet-based discussion took place between the participants that has further advanced the objectives, mechanisms, and priorities of the proposed network. A technical committee was formed, as well as task groups to work on launching a Web site (www.INTACT-Network.net), publishing a monograph of the Bellagio papers, and developing funding proposals to support future activities of the network that include training workshops on the transmission of collective learning about behavior change in communities to NGO leaders, internships for young scholars interested in advancing their skills in the field, and technical seminars and conferences. A founding document circulated during the summer of 2002 to the group for comment and has been adopted by the network to guide its work.

To provide continuity, Barbara Ibrahim of the Council's West Asia and North Africa region offered the facilities of her Cairo office to coordinate the work of the technical committee in launching the network. Nahid Toubia, president of RAINBO, has offered the resources and experience of RAINBO to help expand network membership, provide technical support to the Web site, and generate phased plans to ensure the network achieves its objectives. The network will be strengthened to the extent that it is able to expand its dynamic membership to include other key institutions and individuals with strengths in FGC research.

Report of Year Five:

During Year Five of the Population Council Program III work on the INTACT Network, the Cairo office of the Population Council continued to serve as the network secretariat. The expansion of the network base of FGC researchers continues. As of August 2004, INTACT membership is composed of 220 individuals. This active group communicates via INTACT's website, and members are updated regularly with monthly email info bulletins. Membership affiliation is comprised of representatives from international and national organizations, as well as distinguished scholars, independent researchers, and gender-rights activists. These include USAID's Inter-Agency Working Group on FGC, the Inter-Africa Committee and numerous others. (For a complete list of INTACT Network affiliations to academic institutions and international organizations, please contact Mona Bur, Program Assistant for INTACT at the following email address; mbur@pccairo.org.)

INTACT's Web site and listserv, launched in June 2003, contains free-access pages that perform multiple functions and offer the following features to serve researchers and research-interested managers and policymakers, as well as the interested public:

- Publication of research findings, links to FGC bibliographies, newly published papers and working papers, presentations on FGC, reports and paper abstracts. Site currently contains English and Arabic bibliographies on FGC.
- A directory of FGC researchers including their contact information and research interests. Egypt and Sudan-specific Web pages exist, and other country-specific directories are under construction
- Papers and working papers, presentations on FGC, reports and paper abstracts. Site currently contains English and Arabic bibliographies on FGC.
- Announcements of funding opportunities for research, fellowships, technical workshops and other news of relevance for members;
- Offering a research news board and message forum where participants can post inquiries and exchange information on an immediate basis, regarding study design, ethical matters, or analytic queries;
- Providing links to FGC interventions and initiatives that are consistent with our mission.

In support of technical training of NGO leaders working to eliminate FGC, the INTACT Network served as a sponsor of the Pilot Regional Training on Design, Monitoring and Evaluation of Anti FGC Projects Using the Women's Empowerment Community Consensus Framework, organized by RAINBO and held in Cairo on March 9–11, 2004. Approximately 24 regional participants attended.

In an effort to address advances in research, identify gaps in FGC research, and foster exchange of expertise, INTACT is organizing its first international research seminar, scheduled to take place on October 10–12, in Alexandria, Egypt. During June and July, a call for papers was widely distributed and over 20 abstracts were received for consideration by the program committee. The seminar will bring together regional and international expertise to assess current research on the relationship between FGM/C and male/female sexuality. This meeting also addresses how research findings can improve counseling for women and men affected by FGC. Summaries will be posted to the Web site and published if additional funding is available.

Implementing Organization(s): Population Council

Collaborating Organization(s): Frontiers in Reproductive Health
RAINBO

Activity Funding: Special Initiatives Core

Contribution to Results Framework: IR 2.1

Mission-Funded Initiatives

Program Summary

One feature of the Population Council Program III (PCP3) cooperative agreement is its ability to channel USAID mission funds to Population Council International Programs Division (IPD) field activities that fit within the PCP3's results framework.

During Year One, two such activities were funded. The Regional Economic Development Services Office for East and Southern Africa (REDSO/ESA) mission contributed \$75,000 to efforts of IPD's Gender, Family, and Development program in Kenya to create fact sheets on various aspects of girls' lives in East and Southern Africa and to carry out case studies of successful livelihood programs for young women in Kenya. The USAID/Egypt Mission contributed almost \$89,000 toward Youth Livelihoods in Egypt, a two-year study by IPD's Cairo office on young women's labor market opportunities with the goal of identifying policy interventions that would delay marriage and childbearing sufficiently to create conditions in which more "successful" transitions to adulthood could occur.

During Year Three, USAID/Mali requested assistance from IPD's former West and Central Africa regional office and contributed \$300,000 for studies to gain a better understanding of the trends in contraceptive use in Mali, and the demand and supply factors responsible for these trends, in order to determine how to reinvigorate the national family planning program and make available high-quality and sustainable family planning services to all who need them, thereby reducing the unmet need for family planning in Mali.

Late in Year Three, USAID/Mali requested a follow-on project to disseminate the information gleaned by the previous study and obligated \$100,000 to the effort to inform regional and district health service providers of the major findings of the study, and to enhance use of these findings by sharing and analyzing them and compiling program managers' recommendations for future actions.

During Year Four, the USAID/Mali dissemination project continued. The USAID/Brazil Mission obligated \$475,000 in support of two projects to test HIV/AIDS prevention and care for vulnerable populations in the regions of Brazil bordering on other countries. These projects continued a body of work the Brazil Mission had funded since Year Two under the auspices of the Expanding Contraceptive Choice project. USAID/Cambodia obligated \$200,000 for the Council to provide operations research for the USAID/Cambodia Office of Public Health's new Population, Health, and Nutrition (PHN) strategy for 2002–05. Through operations research the project will contribute to strengthening the capacity of Cambodia's health system to provide a basic package of essential health services in predominantly rural areas.

Year Five saw the continuation of collaboration with USAID/Brazil, as it provided \$700,000 in new funding for the continuation of research regarding HIV/AIDS in Brazil. Activities funded in Year Four by USAID/Cambodia were initiated in Year Five. Almost \$28,000 of USAID/India funds obligated for activities under the ECC project in Year One were programmed during Year Five by IPD/New Delhi, for formative research whose findings will contribute to an operations research project on adolescent reproductive health in Uttaranchal.

Operations Research Support for USAID/Cambodia's HIV/AIDS and Reproductive and Child Health Program

Project #05828

Country/ies: Cambodia

Technical Coord.: Philip Guest

Period: November 2003–August 2004

Objective: To strengthen, through operations research, the capacity of the health system in Cambodia to provide a basic package of essential health services in predominantly rural areas.

Activity Description:

USAID/Cambodia's Office of Public Health and its nine Cambodia-based partners (cooperating agencies and grantees) have completed three-year and annual workplans for information and service delivery activities under the new Population, Health, and Nutrition (PHN) strategy for 2002-05. These activities began in October 2002 and will run for three years.

The Population Council will coordinate and collaborate with URC, a recently selected partner, to carry out formative research for operations research, which will include identifying - and solving through applied research - problems associated with the operation of various components of the national health system (service delivery; information, education, and communication services; behavioral change communication, management, and supervision; training; management information systems, logistics; and referrals). The Council will also provide technical assistance to local partners to help identify operations research issues associated with their information and service delivery activities and design methods to monitor and evaluate the impact of these activities. Other activities will include capacity building for operations research and assistance in preparing and disseminating a report on the results of the research.

Report of Year Five:

Working with URC and the USAID mission, two problems related to the delivery of reproductive health services that required formative research in order to design operations research were identified. One of these problems, the delivery of RTI/STI care and prevention services, was selected for further in-depth study. A local partner, the Reproductive Health Association of Cambodia (RHAC), was selected to undertake the research. The research design developed was a situation analysis of RTI/STI services provided in six provinces in Cambodia. The capacity to undertake research was strengthened through training in research methods provided by the Population Council of RHAC staff. Technical assistance was provided to RHAC staff at all stages of the research, including instrument development, field work, data entry, data analysis and report writing. The Population Council also worked with RHAC to develop the dissemination strategy and materials for the dissemination workshop. The outcome of the research was a technical report that provides recommended interventions to improve the provision of RTI/STI services. The results of these interventions could be assessed through operations research. The Population Council has also worked with URC to define several other issues that require operations research.

Implementing Organization(s): Reproductive Health Association of Cambodia (RHAC) (I04.06A)
Population Council

Collaborating Organization(s): University Research Corp. (URC)

Activity Funding: Field Support

Contribution to Results Framework: IR 3.1

Targeting Truck Drivers for STI/HIV/AIDS Prevention, Testing, and Treatment in Foz do Iguaçu (Paraná State) and Uruguaiiana (Rio Grande do Sul State)

Project #05827

Country/ies: Brazil

Technical Coord.: Juan Diaz

Period: December 2002–August 2005

Objective: To reduce risk behaviors and STI/HIV transmission among border crossing truck drivers crossing by improving access to condoms, testing services, and prevention information, and to determine the effectiveness of a marketing and voluntary counseling and testing (VCT) campaign for HIV prevention in this population; to design a logistics system to guarantee high-quality health treatment for HIV-positive truck drivers.

Activity Description:

In late 2000 the Brazil Ministry of Health, concerned about the growing number of HIV infections and insufficient HIV/AIDS services in the border regions of Brazil, proposed a collaboration with the Population Council to perform an assessment of HIV/AIDS in the border regions. The study (“Strategic Assessment of STI/HIV Transmission in the Brazil Border Regions: Stage 1,” May 2001–June 2002) was a Stage 1 assessment based on WHO’s Contraceptive Strategic Assessment Framework.

Two southern municipalities participated in the assessment: Foz do Iguaçu, which shares a border with Argentina and Paraguay, and Uruguaiiana, which shares a border with Argentina and Uruguay. Assessment findings in both Foz do Iguaçu and Uruguaiiana documented an enormous amount of movement of goods and people across the borders and revealed that the extremely mobile population of truck drivers who cross the highly traveled southern borders of Brazil have little to no access to HIV/AIDS prevention, testing, and treatment services. Because of the mobile nature of their profession, which lends itself to exposure to prostitution, truck drivers are a vulnerable group for STI/HIV/AIDS infection and a bridge population for the spread of STIs/HIV.

This three-and-a-half-year project, one of three comprising Stage 2 of the Strategic Assessment of STI/HIV Transmission in the Brazil Border Regions, seeks to learn more about perceptions of HIV and risk behaviors in this vulnerable population; arm truck drivers with improved access to information, testing, and counseling services; increase their knowledge of their HIV status, mechanisms of STI/HIV/AIDS prevention, and their risk; and, ultimately, increase the frequency of consistent condom use.

Report of Year Five:

The project in Foz do Iguaçu experienced some delays in the opening of the counseling and testing health unit at the customs station due to late arrival of the mobile unit at the study site as well as extended staff training. The clinic was set up in August and staff completed training in September 2003. Actual activities in the trailer were initiated September 30. From the very beginning there was a high demand for services from the truck drivers who were very interested in the information made available.

There were also delays in data entry and analysis from the baseline questionnaire, as data cleaning required more time than estimated. Preliminary data on the baseline questionnaire were presented at the World AIDS Conference in Bangkok (two oral presentations and a one poster). The data analysis, initiated in May 2004 is ongoing.

By the end of June 2004, 1,324 truck drivers were counseled and tested for HIV and more than 41 had received syndromic approach diagnosis and treatment. The return rate for receiving the result of the test was more than 85%, however, a considerable proportion returned later than appointed because they were traveling. In addition, truck drivers attended lectures on the prevention of STIs and other diseases and were able to have their blood pressure measured and glucose tests performed. All truckers, whether participating or not as volunteers, received condoms after any educational contact. The total number of condoms distributed was 16,225. The group educational activities reached 1,816 truckers. More than 6,500 educational booklets were distributed. The personnel working in the customs area also had the opportunity of access to the services provided at the trailer and we gave 75 consultations to these personnel.

In addition, close to the trailer, the project installed a TV set where truckers can watch films and have the opportunity to discuss health issues. The educational activities are broad in scope but the educators focus the messages on condom use and safe sex.

Four participants tested positive for HIV and 50 men tested positive for syphilis.

Mr. Michael Burkly, from the USAID Mission in Brazil, and two U.S. Senators visited the project and were highly impressed by the quality of services given and the impact that the project is having in the truck driver population. Mr. Burkly committed himself to try to look for additional funds to maintain the trailer working after the research project has ended.

Implementing Organization(s): Population Council

Collaborating Organization(s): Brazilian Truck Drivers' Union

AIDS Solidarity Action Network (NASA)

Brazil Ministry of Health—National Coordination on STI/AIDS, Foz do Iguaçu region

DKT

Activity Funding: Field Support

Contribution to Results Framework: IR 1.2

Improving the Quality of STI/HIV/AIDS Prevention in the Brazil/Bolivia Border Region of Corumbá/Puerto Suárez

Project #05826

Country/ies: Brazil

Technical Coord.: Juan Diaz

Period: November 2002–August 2005

Objective: To reduce the risk of STI/HIV/AIDS transmission among vulnerable populations in Corumbá and the neighboring Bolivian municipality by increasing testing and treatment for sexually transmitted infections (STIs) and decreasing risk behaviors through adoption of consistent condom use.

Activity Description:

In late 2000 the Brazil Ministry of Health, concerned about the growing number of HIV infections and insufficient HIV/AIDS services in the border regions of the country, proposed a collaboration with the Population Council to perform an assessment of HIV/AIDS in the border regions. The study (“Strategic Assessment of STI/HIV Transmission in the Border Regions of Brazil: Stage 1,” May 2001–June 2002) was a Stage 1 assessment based on WHO’s Contraceptive Strategic Assessment Framework, which was adapted to explore the cultural context of transmission of STIs and HIV and the service delivery system in six border municipalities in order to develop strategies for improving prevention, diagnosis, and treatment. Results showed that these regions are indeed lacking in STI/HIV/AIDS services and prevention programs. This lack was especially prominent among marginalized populations.

One of the municipalities included in the assessment was Corumbá, a region in western Brazil that shares a river border with the Bolivian municipality of Puerto Suárez. Corumbá is a relatively small town with a large floating population. Many are attracted to Corumbá by the availability of cheap drugs (drug use has had a profound effect on the AIDS epidemic in Corumbá). In addition, the fishing and eco-tourism industries attract 75,000 tourists a year to Corumbá. Together, these characteristics have stimulated a parallel growth in sex commerce. Despite the proliferation of the commercial sex industry, the current municipal AIDS program has few resources to expand actions that target commercial sex workers, whose activities span the border into Bolivia where there are no STI/HIV-related services at all.

This three-year project, one of three comprising Stage 2 of the Strategic Assessment of STI/HIV Transmission in the Brazil Border Regions, seeks to reduce the risk of STI/HIV/AIDS transmission among high-risk populations both in Corumbá and the neighboring Bolivian municipality by decreasing risk behaviors through the adoption of consistent condom use. The strategy includes four basic components: availability of free condoms; condom promotion where commercial sex work occurs and in the general population; improved access to voluntary counseling and testing; and improved access to treatment for STIs in addition to monitoring and treatment of the HIV-positive population.

Report of Year Five:

During Year Five of the Population Council Program III the project was implemented, following delays in the anticipated start date for data collection. The first participant was recruited in July 2003. In the first year of the project, 335 participants were enrolled, completed their baseline visit, including all clinical and questionnaires procedures.

Also in Year Five, an amendment was made to the protocol to include behavioral and clinical follow-up

with study subjects every three months instead of every four, extending the visit schedule over one year to five visits for each participant. The IRB approved of the amendment in September of 2003.

In Year Five, 198 participants completed a second study visit, 101 completed a third, and 33 completed a fourth study visit. Questionnaire and clinical exam data was reviewed by study co-investigators and data entered at the Population Council office in Brazil in an ongoing manner. Preliminary, exploratory analyses were carried out every six months and presented to members of the project's advisory committee at the biannual meeting. The project's advisory committee met twice during Year Five. Two abstracts were submitted to the International AIDS Conference in Bangkok and two abstracts were submitted to the Brazilian STI/AIDS Conference.

Educational activities conducted in Year Five included weekly educational visits to venues where commercial sex occurs as well as individual counseling for study participants during clinic visits. The project staff worked with the municipal HIV/AIDS program to increase access of high-risk populations to HIV prevention, diagnosis, and treatment services for enrolled participants.

Data collection and educational activities will be sustained into Year Six to assure recruitment of the target five hundred participants and to complete follow-up, perform data analysis, and write up and disseminate the study results.

Implementing Organization(s): Population Council

Collaborating Organization(s): Rede Brasileira de Profissionais do Sexo

Pathfinder International

Brazil Ministry of Health—National Coordination on STI/AIDS

DKT

Activity Funding: Field Support

Contribution to Results Framework: IR 1.2

Technical Assistance for the Implementation of the USAID Brazil Research Strategy on STI/HIV/AIDS in Brazil

Project #44804

Country/ies: Brazil

Technical Coord.: Juan Diaz

Period: April 2004–June 2005

Objective: Provide technical assistance for the development and implementation of the research strategy of the USAID/MOH Consortium

Activity Description:

The Population Council's technical assistance will consist of the following:

1. Collaboration on the preparation of the proposal, writing the methodology section and reviewing all other sections.
2. Collaboration in the preparation of the research instruments for the baseline assessment. This will include an adaptation of the questionnaires and other research instruments used in the Foz do Iguaçu project. BEMFAM has also developed some questionnaires for truck drivers and the instruments will actually be a combination of the two questionnaires, selecting, from each one, those areas that worked better. The instruments for voluntary testing and counseling (VCT) and clinic records will be the same as in the Foz do Iguaçu project with minor modifications. In addition, the Population Council will train the field workers and will monitor the data collection and other field activities.
3. Training of the research team. The staff working in Foz do Iguaçu has extensive experience in training and will be in charge of this aspect of the project with the collaboration of a team from the Ministry of Health (MOH) who will consult on some specific issues.
4. Supervision and monitoring. Juan Díaz, principle investigator, and Cristina Ogura, local coordinator of the project in Foz do Iguaçu will supervise the project procedures during the process.
5. The Population Council will work together with BEMFAM in the evaluation of the project and writing of the report and publications.

Report of Year Five:

In April 2004, we participated in a meeting with all the research personnel of Bemfam led by Elizabeth Ferraz, and the Social Marketing Department Director, Mr. Mauro Mendonça. At this meeting, we defined the main components of the project, which will be the evaluation of an educational campaign, complemented by a social marketing campaign on sexual behavior and condom use in truck drivers in Uberlandia. Uberlandia is a city where there is a great concentration of truck drivers because it is a very big distribution center.

In the meeting it was also decided that the evaluation would be done through a pre and post intervention questionnaire. The questionnaires used in the baseline study in Foz do Iguaçu will be used for this purpose. A first version of the questionnaires was prepared and pre-tested in July.

Implementing Organization(s): Population Council

Collaborating Organization(s): Brazil Ministry of Health
BEMFAM

Activity Funding: Field Support

Contribution to Results Framework: IR 2.1

Stalled Fertility Transition in Egypt

Project #06011

Country/ies: Egypt
Technical Coord.: John Casterline, Barbara Ibrahim, Rania Roushdy
Period: July 2003–December 2004
Objective: To better understand the current slow pace of fertility decline in Egypt and to identify policies that might accelerate the decline.

Activity Description:

The research will investigate two interrelated sets of questions. First, fertility has declined slowly in Egypt during the past decade and remains above three births per woman. What are the prospects for acceleration of the decline? What are the obstacles to further decline? What policies might facilitate more rapid decline? Second, economic growth in Egypt is sluggish, at best, and a large proportion of the population remains in poverty. What are the links between household poverty, underemployment, and fertility? What impact does poverty have on reproductive health and fertility goals and decisions? How are household economic circumstances related to the pace of fertility decline?

To address these and related questions, survey data will be collected from a nationally representative sample of the entire country. Two population subgroups will be interviewed: (1) women of reproductive age; and (2) young, unmarried adults (male and female). In addition to standard fertility survey information, more detailed data will be gathered from these subgroups.

Women of reproductive age will be asked to provide information on the economic status of the household; their attitudes regarding childbearing, including the perceived costs and benefits of children (and, in particular, the costs and benefits of having three or more children); how childbearing relates to other personal and family goals and its place in respondents' larger value systems; and obstacles to using contraception, including access to and quality of services, social costs, and fear of health side effects.

Young unmarried adults will be asked to provide information on their aspirations for marriage and parenting, including the timing of marriage, first birth, and the spacing of children; and the way these aspirations relate to their educational and employment aspirations, as well as their personal values.

Data will be analyzed with the aim of ascertaining the primary reasons why fertility remains above three births per woman in Egypt and developing policies that might stimulate more rapid fertility decline.

A report will be prepared and submitted to USAID.

Report of Year Five:

The Egypt Mission MAARD in support of this activity was scheduled to be allocated in July 2003. However, the funds were not actually obligated to the Population Council Program III until April 2004.

John Casterline and Rania Roushdy started developing the research design and tools including the questionnaires in July 2003, before ensuring the funds' availability from USAID. Pre-testing of the draft questionnaires could not be started before December 2003, when limited funding was obtained through the Population Council Cairo Office from Mellon and CIDA. Delays in funding ultimately caused the fieldwork to be pushed back until mid April 2004. When the obligation to the PCP3 was officially

received, a subaward was awarded to the CDC, and they conducted the fieldwork and simultaneously supervised the data processing through late June 2004.

Fieldwork finalization, data cleaning and analysis, and writing of the final report will all be completed no later than September 2004. Dissemination activities under this project are planned for December 2004, and additional dissemination activities to be funded by a supplemental award (through another funding mechanism) are currently under discussion.

Implementing Organization(s): Cairo Demographic Center (CDC) (I04.12A)
Population Council

Activity Funding: MAARD

Contribution to Results Framework: IR 2.1

Addressing Adolescent Reproductive Health Needs: An In-Depth Study of the Gate Keepers in Uttaranchal

Project #44504

Country/ies: India

Technical Coord.: M.E. Khan

Period: April 2004–December 2004

Objective: To assess the opinions of different gatekeepers in Uttaranchal, India about introducing reproductive health education for adolescent boys and girls.

Activity Description:

In order to assess the opinions of different gatekeepers in Uttaranchal, India about introducing reproductive health education for adolescent boys and girls, the study will collect data from parents, teachers, community leaders (formal as well as informal), and religious leaders. Selected development officials have also been included in the study to assess how they could contribute to this effort. The findings of the study will contribute to initiation of an operations research study addressing the reproductive health needs of young males and adolescent boys.

Both qualitative and quantitative methods are being used to collect relevant information. The prime methods include in-depth interviews, focus group discussion and self administered questionnaire to selected school students. Data will be collected at different levels. At district headquarters, the officials who are being interviewed belong to general administration, education, health, Panchayat, and ICDS. Similarly, corresponding officials will be interviewed at Block level. At village level, formal and informal community leaders (Panchayat, school teachers, religious leaders, youth leaders of various clubs and association), and parents, as well as a sample of adolescent boys, will be interviewed.

The interviews will seek to find out (1) views and perceptions on the need of such education for adolescents boys and girls; (2) views and perceptions on how best such a program could be implemented: should it be included in school curriculum? what other methods could be used to reach both in- and out-of-school boys and girls?; (3) what role do they feel they could play in such effort? are they willing to participate in the implementation of the program?; (4) what are the topics which they feel should be given special attention?; (5) would they like to receive some orientation on those subjects so that they could help guide their children or community workers to support the initiative?; (6) what are the local and community resources which could be mobilized for introducing and sustaining such an initiative?

Report of Year Five:

Due to difficulties in finding a suitable principal investigator, this activity experienced a delay in project commencement. A number of tools and guidelines have been developed for qualitative data collection, so the activity is now poised for rapid implementation.

Implementing Organization(s): Population Council

Activity Funding: Field Support

Contribution to Results Framework: IR 3.1

From Pilot Interventions to Regional Programs: Expanding Contraceptive Choice and Improving Quality of Care in the Copperbelt

Project #03262

Country/ies: Zambia

Technical Coord.: John Skibiak

Period: June 2001–August 2005

Objective: To expand contraceptive choice and increase the availability of high-quality reproductive health services across eight rural and periurban districts of the Copperbelt; to field test a model for scaling up reproductive health interventions; and to support ongoing discussions over the approval and registration of Depo-Provera® and emergency contraception and to serve as a model for the introduction of these methods at the national level.

Activity Description:

Note: This activity was formerly entitled “Expanding Contraceptive Choice Demonstration Project in the Copperbelt Province of Zambia: Scaling Up”.

In May 2002 the Copperbelt Provincial Health Office launched a two-year effort to scale up a package of service delivery interventions, previously introduced under an Expanding Contraceptive Choice (ECC) pilot study. The intervention, called Pilots to Regional Programs (PRP), has two broad goals: (1) to bring the benefits of the pilot study to thousands of men and women across Zambia’s Copperbelt Province; and (2) to test a model for overcoming barriers that typically undermine efforts to scale up pilot interventions, namely the ability to maintain quality while increasing the quantity of intervention efforts, the need to respond meaningfully to larger, more heterogeneous social contexts, and the capacity to maximize economies of scale. To overcome these barriers, the model follows a three-phase process for identifying and bringing to scale key service delivery interventions.

During the first phase, the project introduces a package of three intervention components, including (1) expanding the range of contraceptive methods available to family planning clients; (2) training health care workers more effectively and efficiently; and (3) bringing together communities and the health care system so that reproductive health needs can be met more easily and effectively. The primary goal of this first phase is to establish a limited number of demonstration sites or “centers of excellence” in each of the eight participating health districts, thereby providing them with firsthand exposure to the broad range of potential support activities possible through the project. The second phase of the scaling-up effort entails a process of reflection and analysis, culminating in the formulation of district-specific implementation plans. During the third phase, a period of 15 months, the project assembles the human and financial resources needed to implement and sustain the scaling-up effort over time by employing a management structure that is fully integrated with existing public-sector structures.

Report of Year Five:

The current reporting period saw the completion of the second phase of the PRP Initiative and the launch, in early 2004, of the third and final phase. Following a province-wide strategic planning meeting, held in October 2003, the eight participating districts conducted rapid assessments as a first step in developing detailed action plans for scaling up key project interventions.

Since completion of the phase two assessments, PRP staff have worked with districts, providing technical

and financial support to implement their action plans. The bulk of support has been in three areas: training, community outreach, and equipment provision. In addition to general refresher training in basic family planning methods, PRP staff trained 60 CBD workers, and brought on board 107 clinic- and community-based providers of the standard days method—the fastest-growing method in rural Copperbelt.

This reporting period has also been notable for the introduction and/or expansion of two new methods: Depo-Provera and emergency contraception (EC). In early 2004, after nearly 10 years of advocacy on the part of USAID, PRP and its preceding “Stage II” pilot study, Zambia’s Drug and Poisons Board finally approved the registration of Depo Provera. It also authorized the repackaging of 4,000 units of EC pills for use in the study area. Both activities were significant achievements and their realization has helped to complete the application of the PRP’s “minimal method mix” in 40 health care facilities, across all 8 Copperbelt Districts.

Finally, PRP staff have actively sensitized communities to the scaling-up of project-related interventions and have forged new partnerships and cost-sharing agreements among participating districts. Training activities, for example, are now being carried out jointly, with participating districts pooling resources and districts are beginning to waive the fees previously charged to family planning clients referred from other districts. Finally, PRP procured and is in the process of distributing supplies and equipment to support district interventions.

The results of these training, sensitization and service delivery efforts are evident in the Copperbelt Province’s MIS statistics, which continue to stand out at a national level. During the current reporting period, new acceptors per month in the PRP catchment area has averaged a 64 percent increase over the figure for the previous period. Meanwhile, the average number of continuing acceptors has increased by nearly 150 percent.

Originally designed as a two-year effort, PRP is today viewed in Zambia as the most innovative, costeffective, and indeed successful public sector program for scaling-up high-quality family planning services. Nonetheless, PRP is, in certain critical areas, behind schedule. The 4-5 month delay in the signing of the project agreement coupled with the routine constraints of operating within public sector policies and procedures have delayed the implementation of certain innovations. In addition to delays, PRP’s success has led to calls for a national dissemination of project results and an expansion of efforts to increase dual protection and/or method use—neither of which were included within the initial scope of work. For these reasons, the Zambia Central Board of Health requested and received a one-year, no-cost extension, which will allow the PRP Initiative to complete all outstanding program activities by April 2005.

Implementing Organization(s): Copperbelt Provincial Health Office, Zambia Central Board of Health (I02.16A)
Population Council

Collaborating Organization(s): Georgetown University Institute for Reproductive Health
World Health Organization

Activity Funding: Field Support

Contribution to Results Framework: IR 1.2

Searching for Synergies: Dual Protection Within the Context of Provider-Dependent Contraception

Project #03265

Country/ies: Zambia

Technical Coord.: John Skibiak

Period: February 2003–August 2005

Objective: To determine whether a potential synergy exists between highly provider-dependent contraceptive methods and other protective behaviors as a means of reducing the risk of STI/HIV transmission.

Activity Description:

This study will attempt to explore the potential synergy that exists between highly provider-dependent contraceptive methods and other protective behaviors, including but not limited to use of condoms. It will do so by capitalizing on the technical attributes of certain nonprotective methods to make possible a discussion of dual protection that is emotionally neutral and nonthreatening - one that can lift the burden of condom use from the shoulders of women alone.

The study intends to achieve this by providing women who choose any surgical or highly provider-dependent contraceptive method (specifically the IUD, Norplant®, or voluntary surgical contraception [VSC]) with the option of using the “seriousness” of the procedure as a pretext for inviting their male partners to join in facility-based discussions on a variety of method-specific issues, the most important of which will address risk of sexually transmitted infections (STIs), including HIV.

The study’s hypothesis is that IUD/Norplant/VSC couples in which the male partner has been involved in discussions and counseling will be more successful at adopting dual protection and/or other strategies to protect themselves against STIs than those who do not. To test the hypothesis the study will address the following questions: (1) Does the perceived gravity of a provider-dependent method serve as an effective pretext for involving men in counseling on dual protection? (2) Does male involvement change male and/or female partner perceptions of reproductive health risks, including risk of STI transmission? and (3) Does male involvement change the health-seeking behavior of male and/or female partners through increased monogamy or use of dual methods?

Report of Year Five:

The proposed launch of this study was undermined last year by the discovery of dramatic declines in the use of what has been referred to as “highly provider-dependent contraceptive methods (DPD). A survey carried out in September 2003 found that national public-sector stocks of Norplant® had expired, while severe staff shortages at participating tertiary health institutions had reduced the delivery of IUDs and sterilizations to a minimum.

In early 2004, following the departure of the Project Officer charged with developing the study protocol, discussions were held with USAID/Zambia to determine whether to proceed with the current study. While both sides acknowledged that the conditions surrounding the original design of the study had changed, the Mission felt that the issue of dual protection remained critical and that alternative options should be explored to test key hypotheses of the original study. The Mission agreed, therefore, with a proposal to implement study interventions at a limited number of health care facilities currently participating in the WHO/USAID-sponsored PRP Initiative. In several respects, these facilities offer an even more appropriate and cost-effective context for exploring the issue of dual protection. Through the PRP Initiative, they

already have in place systems for monitoring dual protection; and every participating facility has at least two year's worth of baseline data for measuring changes resulting from study interventions. In addition, many health care facilities in the PRP study area are already offering the IUD on site and BTL through referrals. What is more, the PRP Initiative has been chosen by the Central Board of Health as one of several key venues for the reintroduction of implant (Jadelle) services into Zambia. And finally, because the promotion of dual protection has, for the last two years, formed an integral part of ongoing community-based IEC efforts, the interventions would simply entail a shift to more focused male involvement.

Over the coming two months, therefore, staff of the Council and PRP Initiative will identify 2–3 appropriate health care facilities in four Districts (Chililabombwe, Kalulushi, Luanshya, and Chingola) where IUD, BTL and implants are currently (or soon to be available). Together with staff of the participating facilities, a plan of action will be developed to test original hypotheses, while at the same time, dovetailing, wherever possible, new and existing interventions. The new action plan will maintain the original 3 month intervention period so that data analysis and write-up can be completed by July/August 2005.

Implementing Organization(s): Population Council

Collaborating Organization(s): Ndola Central Hospital

University Teaching Hospital, Lusaka

Ndola District Health Management Board

Activity Funding: Field Support

Contribution to Results Framework: IR 3.1

Reducing Unwanted Pregnancy Among Victims of Sexual Assault: New Windows of Opportunity for Emergency Contraception (formerly Operations Research on Emergency Contraception in Zambia)

Project #44103

Country/ies: Zambia

Technical Coord.: John Skibiak

Period: July 2004–July 2005

Objective: To better understand the support-seeking behaviors of sexual assault victims; to demonstrate the feasibility of a simple intervention that guarantees timely access to quality EC services at FPC's and familiarizes FPC staff with the full range of support services available to assault victims.

Activity Description:

This study is designed to test the feasibility of an intervention to ensure that no window of opportunity closes before a victim of sexual abuse receives the services she needs—particularly services that can prevent an unwanted pregnancy. The intervention comprises two components. First, it will train staff at selected “first points of contact” (FPC) in Lusaka and Ndola to provide EC services to rape victims who might not otherwise receive them within 72 hours of unprotected sex. It will also strengthen the FPC's capacity to offer such a service, by supporting efforts at information dissemination and community outreach. Initially, FPCs will include the Victim Support Unit of the Zambia Police Force, district health clinics and the two principal referral hospitals in Lusaka and Ndola

The second intervention will be to enhance victims' access to support services in general—even those that cannot be directly provided at the FPC. Training non-health staff to administer EC will not diminish the role of health sector insofar as only they can provide a complete package of essential health care services. But unless FPC staff know what these services are, they are unlikely to offer a convincing argument on the need to seek proper medical care or, for that matter, legal support, or even police protection. The second activity under this study, therefore will be to orient all FPC staff to the full range of health, forensic, legal and psycho-social services available to victims of sexual assault and to the institutions that provide them.

In keeping with the philosophy of the WHO Strategic Approach to Contraceptive Introduction, this intervention seeks to use the expansion of EC services as a vehicle to strengthen the support system in general. It also uses the strengthened support system as a basis for re-introducing, after a lapse of nearly five years, a dedicated EC pill (ECP) into Zambia's public sector service delivery system. The study will support a host of initiatives already underway in Zambia to combat gender-based violence and address its consequences. These include a new Taskforce on Gender-based Violence, chaired by the Zambia Central Board of Health; a multi-year “Access to Justice Program, support by the Development Services and Initiatives/Southern Africa (DSI); and various initiatives being implemented by organizations such as CARE International, Women for Justice, and the Juvenile Court.

Coordinated by the Population Council, the intervention described will be a collaborative effort among a host of organizations, including the Zambia Police Service, University Teaching Hospital and/or Ndola Central Hospital, and the Zambia Central Board of Health. In addition, it will benefit from financial and technical support provided by USAID/Zambia and ECafrique, the Africa-wide network on emergency contraception.

Report of Year Five:

As this project has a start date of July 1, 2004, no activities were completed in Year Five. Delays for the initiation of this activity arose, as the scope of work for this project depended on a WHO strategic planning meeting that was pushed back to February 2004. A visit to Zambia in April 2004 provided the final details for the proposal.

Implementing Organization(s): Population Council

Collaborating Organization(s): Ecafrigue

Zambia Central Board of Health

Lusaka District Health Management Board

Ndola Central Hospital

University Teaching Hospital, Lusaka

Zambia Police Forces, Victim Support Unit

Activity Funding: Field Support

Contribution to Results Framework: IR 2.1

Experimental Family Planning Studies in Rural Africa

Program Summary

The Population Council's Experimental Family Planning Studies in Rural Africa program has two major components: the Community Health and Family Planning project (CHFP) and the Community-Based Health Planning and Services initiative (CHPS) in Ghana. The CHFP tests innovative strategies for health and family planning service delivery in rural areas of the country; CHPS is a nationwide service-delivery strategy modeled on the CHFP.

The Community Health and Family Planning Project

The impact of family planning programs on fertility in rural Africa has been debated in the policy literature for three decades; a more recent debate surrounds the question of whether expanding access to health services will improve child survival. To help resolve these issues, the Navrongo Health Research Centre (NHRC) in northern Ghana, under a subagreement with the Council, launched the CHFP—a field experiment testing the relative demographic impact of four approaches to providing primary health care and family planning services in the rural, traditional district surrounding the town of Navrongo. The CHFP began as a pilot project in 1994; it was scaled up to a district-wide trial in 1996.

Preliminary results showed that CHFP activities improved the impact of health and family planning services, reducing fertility and mortality rates. Three-and-a-half years into the project, the fertility rate in the most intensive treatment area was nearly one birth per woman lower than the rate in comparison areas. In areas where nurses were assigned to villages, early and late childhood mortality was 38 percent lower than in comparison areas. To assess the long-term effects of CHFP interventions, researchers must run the experiment long enough to measure its full demographic impact; to this end, experimental operations continued through 2003 and observation continued into 2004.

In 1998, under the same subagreement with the Council, the NHRC launched a five-year experimental project testing the effect of mobilizing communities to reduce the practice of female genital cutting (FGC). This project has revealed ways in which traditional social institutions support the practice of FGC, pointing to potentially promising strategies for community-based interventions.

The Community-Based Health Planning and Services Initiative

In response to evidence of CHFP success, the Ghana Ministry of Health (MOH) adopted the CHFP as a model for reforming community health and family planning services at a national level. In 1999 the MOH launched CHPS to replicate CHFP services in all of Ghana's 110 districts.

CHPS comprises national consensus-building mechanisms, a liaison program that arranges training opportunities for health management teams from regions where there is interest in CHPS, and a field program that develops CHPS demonstration capabilities in lead districts. This initiative has shown that national policy and programs in Ghana can be reformed successfully by scaling up experimental projects—an approach that may work in other African settings as well.

The CHFP Dissemination Unit, based at the NHRC, links CHPS to the CHFP, providing information, consultation, and training services that bridge the programs. The unit works to promote effective

implementation of CHPS and fosters communication aiming to improve health and family planning services in Ghana.

The Council's contribution to CHPS under the PCP3 focused on three areas: (1) systematic documentation of CHPS implementation, including its pace and barriers to progress; (2) technical assistance to develop a CHPS Secretariat to oversee the initiative; and (3) technical assistance to specific CHPS implementation and monitoring/evaluation activities.

USAID provided major funding for the Council's Experimental Family Planning Studies in Rural Africa program. The CHFP was supported by USAID core funds; CHPS and the CHFP Dissemination Unit received funding from USAID/Ghana (field support). With funds from USAID/Ghana, EngenderHealth and INTRAH/PRIME II provided technical support for CHPS service development; the Johns Hopkins University Center for Communication Programs provided training and dissemination materials; and JHPIEGO trained nurses to provide CHPS services.

Technical Assistance to the Navrongo Community Health and Family Planning Project and the Community-Based Health Planning and Services Initiative

Part of project #04700

Country/ies: Ghana

Technical Coord.: James F. Phillips

Period: January 1994–May 2005

Objective: To provide technical support for and research on the activities of the Experimental Family Planning Studies in Rural Africa program.

Activity Description:

This activity encompasses all Population Council technical assistance to the projects of the Experimental Family Planning Studies in Rural Africa program.

Since 1992 the Council has provided technical support to the Ghana MOH to establish a field research station in a rural traditional district and to conduct an experimental study on the demographic impact of community health and family planning services. Originally launched as a pilot project in 1994, the Navrongo Community Health and Family Planning project (CHFP) had become a districtwide experiment by 1996. By 1998 preliminary evidence of project impact led the government of Ghana to adopt Navrongo as the basic model for primary health care in all districts of the country. The Council's Policy Research Division provides continuing technical support to research activities of the Navrongo experiment (see "The Navrongo CHFP") and collaborative support to its dissemination program (see "Disseminating Lessons Learned from the Navrongo CHFP"). Support is also provided to a program of reproductive health research that aims to test the hypothesis that the practice of female genital cutting (FGC) can be reduced through community outreach (see "A Community-Informed Experiment in Preventing FGC Among the Kassena-Nankana of Northern Ghana").

In 1999 the Community-Based Health Planning and Services initiative (CHPS) was created to coordinate the scaling-up process. The initiative now operates in 71 districts, including 20 "lead districts." Council assistance focuses on systematically documenting the pace of CHPS implementation or barriers to CHPS progress, and providing technical assistance to the development of a CHPS Monitoring and Evaluation (M&E) Secretariat to oversee the initiative and develop effective strategies to assess CHPS implementation (see Using Nkwanta District as a Center for Excellence in Developing the CHPS" and "Establishing a CHPS M&E Secretariat and Creating an Appropriate M&E Strategy").

Report of Year Five:

The Council provided technical assistance to the Navrongo Health Research Centre in the following areas:

1. *Demographic analysis of the CHFP Experiment (non-USAID-funded):* Analysis of the 2003 panel survey and the Navrongo Demographic Surveillance System reveals a significant increase in ever use of modern family planning among married women (from less than 1 percent in 1993 to 50 percent in 2003), and a TFR level decrease from 5 births per women in 1993 to 3–3.5 births per woman in 2003.
2. *Demographic analysis of the FGM Eradication Experiment:* Two non-USAID-funded Ghana Fellows served as principal investigator of this project during Year Five: Reshma Naik and Philip Adongo. They were responsible for data collection, analysis, and reporting of the 2003 follow-up survey comparing the two different intervention strategies - education and livelihoods. Results reveal trends since the beginning

of the experiment in 1999 that exposure to problem-focused FGC education strategies was associated with a decrease hazard of FGC of 93 percent relative to no intervention exposure, and combined exposure to both education and livelihood and development strategies was associated with a decreased hazard of circumcision of 94 percent relative to no exposure. Taken individually, the education strategies were determined to have had a significant effect while the livelihood strategies in and of themselves had no appreciable effect.

3. *Support for scaling up:* Council staff collaborated with NHRC and Ghana Fellows to design procedures to scale up the CHFP and FGM experiments. The CHFP scale-up (to begin in late 2004) is designed to end experimental variance and test the hypothesis that CHO and volunteer services in all study cells will lead to similar improvements in fertility and family planning indicators. The FGM scale-up (begun January 2004) is designed to test whether results district-wide confirm the findings in the original treatment communities.

4. *Support to the CHFP Dissemination Unit:* Council staff provided editorial and graphics assistance to the Dissemination Unit for production of the *What Works? What Fails?* and *Pogsara Yia!* newsletter series.

With regards to CHPS technical assistance, highlights include:

1. *District-level Evaluation Surveys (DES):* Technical assistance from a non-USAID-funded Ghana fellow allowed the Nkwanta team to conduct a follow-up survey to its highly successful 2002 baseline assessment. The research analyzes trends in health-seeking behaviors as CHPS implementation has expanded within the district. A consultant was recruited to provide technical assistance to the baseline DES study in the AAK District, and a non-USAID-funded Ghana Fellow seconded to Ghana Health Service Policy, Planning, Monitoring and Evaluation Division (GHS/PPME) has been overseeing the effort in Birim North district.

2. *Strategic Assessments:* Council staff collaborated with the GHS/PPME on qualitative assessments of CHPS workers in the Western and Upper West Regions. Data analysis is currently underway.

3. *Dissemination of Results:* The Council has consistently worked with the CHPS M&E Secretariat on the dissemination of results, within Ghana and internationally. Papers on the CHPS process and its innovations have been presented at annual meetings and at other conferences and consortia. Papers have recently appeared in peer-reviewed journals such as *Studies in Family Planning* and *Health Policy and Planning*.

4. *CHPS M&E database and Web site:* The Council assisted in upgrading and expanding a database that tracks CHPS implementation status nationwide and a website that provides access to CHPS program information and results. The Council assisted the Secretariat since 2001 in the development of these tools.

Implementing Organization(s): Population Council

Collaborating Organization(s): Ghana Health Service

Ghana Ministry of Health (MOH)

Navrongo Health Research Centre (NHRC)

Activity Funding: Field Support & Pop Core

Contribution to Results Framework: IR 3.1

The Navrongo Community Health and Family Planning Project

Part of project #04700

Country/ies: Ghana

Technical Coord.: James F. Phillips

Period: January 1994–April 2005

Objective: To test the hypothesis that fertility and child mortality rates can be reduced through community services in a rural setting in sub-Saharan Africa.

Activity Description:

Note: This activity is carried out through the Population Council's core-funded subaward to the Navrongo Health Research Centre (NHRC). The same subaward also supports "The NDSS: Demographic Surveillance for the CHFP" and "A Community-Informed Experiment in Preventing FGC Among the Kassena-Nankana of Northern Ghana."

For over three decades, there has been general consensus about the need to establish community health and family planning services in Africa, yet there is remarkably little sound scientific evidence that the strategies pursued can reduce mortality and fertility. By the early 1990s, two broad approaches to health care were advocated, one emphasizing the sustainability of volunteer efforts (the UNICEF-sponsored Bamako Initiative) and the other emphasizing the importance of professional paramedical care. The Community Health and Family Planning project (CHFP), fielded by the NHRC, was created to resolve debates surrounding these approaches.

The Navrongo CHFP makes use of a four-celled experimental design. Each approach to health care is pursued independently in respective cells (volunteers only or nurses only), jointly in one cell (both volunteers and nurses), and not at all in a fourth cell, which retains the existing clinical program. Testing these hypotheses in Navrongo is particularly important for national and regional policy deliberations. The region in which the NHRC is located is the poorest and most remote in Ghana. Mortality is high, and women's educational attainment, autonomy, and authority are constrained by marital customs, family-building strategies, and patriarchal systems of gender stratification. If health and family planning services can work in such a setting, they can work anywhere.

By 1997, preliminary evidence from Navrongo suggested that the experiment was having an impact. A single nurse equipped with a motorbike and relocated to a village health center could outperform the staff of an entire subdistrict health center. The volume of health service encounters in study areas increased eightfold, immunization coverage improved, and adoption of family planning increased dramatically. Results were evident in all experimental cells, but the impact of the combined service strategy was particularly compelling.

Report of Year Five:

From September to October 2003, the CHFP team conducted its tenth and final panel survey to assess the experiment's impact on demographic outcomes. Results indicate that fertility within the study district has declined rapidly over the last decade, from 5 births per woman to 3.9. While fertility has declined throughout the district, fertility decline is greater in areas where a health professional is present: In the volunteer only cell, current total fertility replacement (TFR) is 4.6; in the CHO-only cell, 3.0; and in the combined (volunteer + CHO) cell, 3.6.

One factor possibly accounting for the general decline in fertility is the increase in contraceptive method use: Roughly 50 percent of currently married women reported ever using a modern contraceptive method. This is a significant increase from the baseline prevalence of less than one percent district wide. However, current use of family planning remains low at 16 percent. One important finding is that the CHO is the most popular source of information of family planning in areas where one is deployed. Research conducted under the PCP3 Agreement has revealed that the primary reason for contraceptive method use is for birth spacing.

As of the 2003 survey, immunization coverage is more than 60 percent. With regards to neonatal vaccination rates, an analysis for the period 1996 to 2001 reveals that roughly one-quarter (23.8 percent) of children received a complete vaccination sequence by age 1 by the end of the analysis period. While this is relatively low compared with rates in developed countries, this proportion represents a doubling in the fully- vaccinated rate since the full-scale CHFP intervention began in 1996 (11.3 percent).

Mortality rates remain high in the Kasena-Nankana district, although it must be noted that they have declined considerably over the last decade. As of 2003, the crude death rate was estimated at 13.58, a decline of 24.1 percent from the 1994/1995 period. The neonatal mortality rate was 31.09 per 1,000 new births in 2003, a decline of 34.5 percent from 1994/1995. The infant mortality rate was 84.66 per 1,000 new births in 2003, a decline of 52.5 percent from 129.1 during the 1994/95 period.

An analysis of contraceptive use denial was anticipated to have been completed during Year 5. Unfortunately this study has had to be postponed due to staffing constraints at the Center. With the completion of the final panel survey report, staff are now available to conduct this analysis. The Council will be working with the NHRC to complete this task during the PCP3 extension period.

In Year 5, the NHRC began what has been referred to as “reversing” the experiment—testing whether ending the variance between all four cells by placing combined CHO+volunteer services in the other three cells will lead to the similar improvements in primary health care and family planning indicators. In order to do this, CHO and volunteers are being introduced into all communities where they currently do not exist. Scaling up planning began in early 2004 with a more comprehensive “roll-out” beginning in late fall.

With regards to cross-national exchanges, dialogue has been slow between the Ghana Health Service, the Council, and the international donor community to generate interest and resources for a pilot intervention. USAID is actively working with the Council on these efforts. The idea has generated interest in a number of countries outside the Sahelian region, and the partners are therefore exploring the possibility of testing the Navrongo model in an east or southern African country as well.

Implementing Organization(s): Navrongo Health Research Centre (NHRC) (CP01.02A)
Population Council

Collaborating Organization(s): Ghana District Health Management Team
Ghana Ministry of Health (MOH)

Activity Funding: Pop Core

Contribution to Results Framework: IR 3.1

The Navrongo Demographic Surveillance System: Demographic Surveillance for the Community Health and Family Planning Project

Part of project #04700

Country/ies: Ghana
Technical Coord.: James F. Phillips
Period: November 2002–June 2004
Objective: To provide accurate and timely data on demographic events for the Community Health and Family Planning project (CHFP).

Activity Description:

Note: This activity is being carried out through the Population Council's core-funded subaward to the Navrongo Health Research Centre (NHRC). The same subaward also supports "The Navrongo CHFP" and "A Community-Informed Experiment in Preventing FGC Among the Kassena-Nankana of Northern Ghana."

An international, interdisciplinary team of scientists has been working for nearly a decade to harness the power of computer technology to increase longitudinal health and population research capacity in developing countries. The common technical platform of these initiatives is a Council-developed computer software generator known as the Household Registration System (HRS), which was field-tested at the NHRC. HRS-generated systems now operate in 16 sites in research stations in Africa and Asia. Software code produced by the HRS serves as the electronic foundation of the Navrongo Demographic Surveillance System (NDSS). This system supports several scientific undertakings at the NHRC, including the Navrongo CHFP, by providing longitudinal data on the course of reproductive and survival changes in Kassena-Nankana District. Recent publications reporting on CHFP demographic impact are NDSS-based.

Financial support to develop and maintain the NDSS was provided by the Rockefeller Foundation, but this funding ended on 30 June 2002 because the foundation decided to end its population program. However, a new Rockefeller Foundation adolescent health initiative is now supporting half of the cost of the system. Other non-CHFP health protocols are funding an additional 30 percent of all NDSS costs. The remaining 20 percent of NDSS costs are borne by the CHFP. The funding is preserving the ability to continue surveillance operations within the Kassena-Nankana District, enabling the NHRC to sustain its general research program, and facilitating CHFP impact assessment. USAID initially allocated core funds to support operation of the NDSS components that feed directly into the CHFP experiment (i.e., that provide the fertility and mortality data linked with the CHFP's annual panel survey) in Year Three of the Population Council Program III (PCP3). However, those funds were not used during Year Three because sufficient funds were available from the Rockefeller grant.

Final Report:

Support to the NDSS by USAID has been critical to ongoing analysis of the fertility and mortality impact of the CHFP. In particular, the NDSS was used by NHRC researchers to assess the affect of mortality decline on reproductive change. The hypothesis was that high fertility in high mortality settings is influenced by the tendency of couples to replace children who have died. Birth and deaths data occurring to children of 43,000 women observed in the NDSS over the July 1993–June 2003 period was analyzed. Results show that child spacing customs may accompany child mortality rather than child replacement. Thus, the fertility impact of child replacement behavior is offset by child spacing customs. Themes from this research have been incorporated into various communication mechanisms of the Community-based

Health Planning and Services (CHPS) Initiative so that results are linked to Ghana's health policy and program development activities.

Implementing Organization(s): Navrongo Health Research Centre (NHRC) (CP01.02A)

Collaborating Organization(s): Ghana Ministry of Health (MOH)

Activity Funding: Pop Core

Contribution to Results Framework: IR 3.1

A Community-Informed Experiment in Preventing Female Genital Cutting Among the Kassena-Nankana of Northern Ghana

Part of project #04700

Country/ies: Ghana

Technical Coord.: James F. Phillips

Period: April 1998–March 2005

Objective: To implement a full-scale experimental program to prevent female genital cutting (FGC), continue surveillance of FGC prevalence, conduct research to enhance understanding of issues contributing to changes in FGC behavior, and assess the impact of the program.

Activity Description:

Note: This activity is carried out through the Population Council's core-funded subaward to the Navrongo Health Research Centre (NHRC). The same subaward also supports "The Navrongo CHFP" and "The NDSS: Demographic Surveillance for the CHFP."

This experimental study tests the hypothesis that FGC can be reduced by community organization and action in a setting where the practice has been nearly universal. Research identified a complex system of support for the practice of FGC that was ingrained in traditional social values and involved all members of society and social strata. A program of "participatory planning" was used to guide development of the intervention with a special focus on women, who were found to be the most active proponents of FGC.

Two distinct strategies were developed: (1) education about the harmful effects of FGC and (2) empowerment of women and girls through increased economic opportunities and skills development. Pilot intervention program activities, completed in October 2000, tested these strategies and clarified ways to mobilize community support and reach all actors in the FGC system.

Report of Year Five:

In Year 5, the project team conducted an analysis using survey data collected throughout the four years of this study (1999–2003). Using a study assessing the role of denial within the experiment (see below), the analysis was designed to control for this variable.

Circumcision prevalence data was collected on a total of 8,473 individuals, and a survival analysis modeling the risk of FGC was run on a sub-set of 4,761 uncircumcised girls interviewed at least twice over the period. Results reveal that exposure to problem-focused FGC education strategies was associated with a decrease hazard of FGC of 93 percent relative to no intervention exposure, and combined exposure to both education and livelihood and development strategies was associated with a decreased hazard of circumcision of 94 percent relative to no exposure. Taken individually, the education strategies were determined to have had a significant effect while the livelihood strategies in and of themselves had no appreciable effect.

Quantitative and qualitative analyses were conducted to assess the impact of denial of circumcision—a problem identified in a year 2000 analysis—on the intervention. Quantitative analysis of the relationship between respondent and interview characteristics and survey response yielded results which point to a consistent positive association between marriage and circumcision prevalence and a negative association between marriage and the probability of a "denial" response. Actual reporting of circumcision is higher among older respondents. Interviewer characteristics influenced reporting of circumcision and intention to

be circumcised. Older interviewers were more likely to record “denial” responses among girls who previously stated that they were circumcised and male interviewers were more likely to record that girls either were circumcised or intended to become circumcised. Lastly, self-reported intention to be circumcised was lowest among respondents who had received exposure to any intervention activity, respondents who were interviewed later within their villages, and respondents who were not currently in school.

The qualitative findings of this study reveal that a number of complex factors influence the phenomenon of response reversal or “denial” of circumcision status. Most striking was the fact that girls are uncertain about the rationale behind the questions and are thus apprehensive about the potential consequences of their responses. Awareness about the law banning the practice is high, so many fear the risk of arrest. In addition, mockery and ridicule is now being re-directed toward those who circumcise. All of these changes have caused circumcised girls to regret their actions, and thus feel sad, angry, or embarrassed when being questioned about them. Additionally, they expressed a strong preference for a female interviewer similar in age to them. The interviewer’s attitude was described as an especially critical and influential factor in determining their final response.

Finally, researchers assessed the impact of denial on intervention strategy. It was concluded that denial had no relation to type of intervention implemented.

Based on this evidence, the NHRC is working, with technical assistance from the Population Council, to scale up the intervention to all areas of the Kassena-Nankana District. While only education strategies were deemed statistically effective, livelihood strategies are also being included, as they are deemed to be beneficial for reasons other than FGM incidence reduction. The FGM team had originally planned the roll-out over a six-month period (January–June 2004). Upon further assessment, it was determined that it would actually take closer to 12 months (January–December 2004). Upon completion of the roll-out, the FGM team hopes to produce a final status report on the scale-up, to be written and submitted to USAID by the end of March 2005.

Subsequent to the scaling up, the NHRC would like to perform an assessment of its impact. Unfortunately, no funding is available for this effort. The Centre is currently discussing the possibility of collaborating with Catholic Relief Services on such an assessment.

Implementing Organization(s): Navrongo Health Research Centre (NHRC) (CP02.11A)
Navrongo Health Research Centre (NHRC) (CP01.02A)

Collaborating Organization(s): Ghana Association of Women’s Welfare
Center for Sustainable Development
ACTIONAID Ghana
National Commission on Women and Development
Ghana District Health Management Team
Ghana Ministry of Health (MOH)

Activity Funding: Pop Core

Contribution to Results Framework: IR 3.1

Disseminating Lessons Learned from the Navrongo Community Health and Family Planning Project

Part of project #06613

Country/ies: Ghana
Technical Coord.: James F. Phillips
Period: January 1997–August 2004
Objective: To orient teams of visitors to the Navrongo Community Health and Family Planning project (CHFP) system of service delivery and to provide support to the national CHFP scaling-up program, known as the Community-Based Health Planning and Services initiative (CHPS).

Activity Description:

Note: This activity is carried out through the Population Council's field support-funded subaward to the NHRC.

In January 1997 the NHRC began to develop a full-scale effort to disseminate information about the CHFP process and its findings, including hosting site visits for interested parties and delivering presentations at national and international conferences and forums. Positive feedback from the preliminary results of the CHFP experiment during the period 1996-2000 led the Ghana MOH to develop the lessons learned from the project into a countrywide initiative for delivering health care to communities throughout Ghana, known as the Community-Based Health Planning and Services initiative. The MOH called upon the NHRC to use its experience implementing and maintaining the CHFP to facilitate the participation of other Ghanaian and outside agencies in the scaling-up process. In October 1999 the Council issued a subaward to the NHRC for the purpose of funding the dissemination activities, including developing materials for training and sharing lessons learned, and providing training (both onsite and at the NHRC) for health professionals implementing CHPS in other regions of Ghana. In addition, the subaward provided a mechanism through which the NHRC could organize and convene CHPS regional and national dissemination conferences, as well as play a role in establishing a CHPS Secretariat at the Ghana Health Service in Accra to guide the nationwide CHPS initiative.

Report of Year Five:

Under the CHFP Dissemination Unit Subaward, the NHRC has coordinated or participated in a series of meetings with policymakers to inform them about the CHFP strategy and to gain consensus for CHPS, the nationwide scaling up of the CHFP experiment. These have included a convening a district directors conference in Cape Coast in 2000, co-coordinating a national health forum on CHPS in 1999 and participating in another held in 2003. In 2003, the Unit collaborated with the CHPS M&E Secretariat to convene a workshop for advanced CHPS districts interested in sharing their experiences with other implementing districts (see M&E write-up for more details). Unit staff have been representing the CHFP at CHPS partners meetings convened by GHS and the USAID Mission throughout the life of the project.

Field exchanges have been conducted by the NHRC to train CHPS implementing districts in the theoretical and practical processes. In all, 28 districts throughout Ghana visited Navrongo. In addition, 12 visits were made to implementing districts by Dissemination Unit staff to assess CHPS progress and provide guidance on further implementation.

The Dissemination Unit has been instrumental in promoting the CHFP in pre-service training programs throughout the north of the country. Consultations and field exchanges were conducted with, among

others, the Tamale Community Training School, the Kintampo Rural Health Training School, the Bolgatanga Upper East Regional Health Training Centre and the Bawku Health Training Center. In addition, technical assistance was provided by the NHRC in creating and providing instruction at the Navrongo Community Health Nurse Training School, established in 2002. Staff involved in the school's development will be collaborating closely with the new CHPS-TA program's staff on its pre-service training program.

In July 2001, the CHFP launched a collaborative program of documentation and dissemination with the Kassena-Nankana DHMT to produce a series of newsletters titled *What Works? What Fails?* The series describes the CHFP experience and results in order to provide training materials for CHPS districts. As of the end of Year 5, 84 *What Works?* notes have been completed. Another series, *Pogsara Yia!* (Girls First!), also began in July 2001. The focus of this series is to inform interested parties in the activities of the FGM Eradication Project coordinated by the CHFP. A total of 16 issues have been published to date. These series are circulated in printed and electronic format on the internet to all Regional Health Offices in Ghana and Directorates of the MOH and GHS in Accra, and to donor and other interested parties in the international arena.

In July–August 2004, the Dissemination Unit will compile one final bound edition of each newsletter series for use by the CHPS-TA program and other parties interested in promoting the CHPS implementation process throughout Africa.

Implementing Organization(s): Navrongo Health Research Centre (NHRC) (CP99.06A)

Collaborating Organization(s): Ghana Ministry of Health (MOH)

Activity Funding: Field Support

Contribution to Results Framework: IR 3.1

Establishing a Community-Based Health Planning and Services Initiative Monitoring and Evaluation (M&E) Secretariat and Creating an Appropriate M&E Strategy

Part of project #06613

Country/ies: Ghana
Technical Coord.: James F. Phillips, Ellie Feinglass
Period: October 2002–May 2005
Objective: To develop a Community-Based Health Planning and Services initiative (CHPS) M&E Secretariat and to design and implement a CHPS M&E system nationwide.

Activity Description:

Note: This activity comprises one part of the Population Council's support for CHPS implementation.

During Year Three of the Population Council Program III, an interim program of monitoring and evaluation was conducted by a CHPS M&E Secretariat based in Ho, Volta Region, that was mandated to develop the M&E component of the national CHPS initiative. The Secretariat and its functions were shifted to a permanent home within the Policy Planning, Monitoring, and Evaluation (PPME) Division of the Ghana Health Service (GHS) in Accra in August 2002.

Report of Year Five:

In January 2001, a database was developed by the Secretariat for recording progress nationwide in implementing CHPS. A form prepared by each district over a 90-day period reports on the pace and coverage of activities by component of the implementation process. The M&E Secretariat distributes hard copies of progress reports every 90 days. As of the Q1 2004 reporting cycle, 104 districts (i.e., 95 percent) had begun CHPS implementation, with at least one step in the process clearly identified. All districts are now providing reports on CHPS implementation progress to the GHS: As of the Q1 2003 reporting cycle, monitoring visits insured that 90 of the districts (i.e., 82 percent) were reporting all information correctly. The remaining districts were visited in 2004.

In 2002, the CHPS M&E Secretariat established the PPME Awards Task Force, chaired by the Director General of the GHS, to prioritize proposals to PPME for funding to innovative districts. Six districts were selected, two (AAK and Birim North) purposely to test the program, and four (Bawku West, Jasikan, Juabeso Bia, and Saboba Chereponi) through a competitive innovators program, coordinated with the NHRC's CHFP Dissemination Unit. The competition was introduced through an innovators workshop convened in February 2004. Between February 2003 and May 2004, the six innovators received awards and have been conducting field exchanges with other CHPS implementing districts. Four of these districts have also been conducting research into the demographic impact of CHPS (see below).

In 2001, the M&E Secretariat embarked on a qualitative research program - a multilevel systems analysis of worker and community reactions to CHPS implementation. Researchers met with district and sub-district medical directors, nurses, and community members in three districts of the Volta Region. In 2002, a second assessment was conducted in the Central Region. Two additional studies were conducted in 2003, in the Western and Upper West Regions (results forthcoming). The results of SAM studies have been used to strengthen the CHPS implementation process within the regions studied and for informing policy decisions regarding CHPS implementation nationwide. Results from Volta and Central Region studies have been disseminated at national and international conferences and disseminated to District and Regional Health Directors throughout Ghana.

In 2002, the Secretariat, in collaboration with the Population Council, the Regional Institute for Population Studies (RIPS), and the Nkwanta DHMT, tested variants of the WHO “60-cluster survey” method to see whether these techniques can be used to assess the effectiveness of CHPS program implementation. The institutions jointly conducted two demonstration projects: one using a district samples and one using a regional sample. The resulting Demographic Evaluation System (DES) toolkit is being used by the Secretariat to gauge CHPS impact in two districts and in Year Five was disseminated nationwide. Results of the initial district DES are being published in the next issue of *Studies in Family Planning*. A final report on the regional DES was just recently published by the Regional Institute for Population Studies and submitted to the Secretariat for evaluation and dissemination. Results from the subsequent district toolkit refinement study were presented at the 2004 Annual Meeting of the Population Association of America (PAA). Three additional surveys using the DES methodology are being planned or currently underway in the Birim North, Jasikan, and Juabeso Bia Districts.

The Secretariat has been very active in dissemination of results. In 2003, a National Health Forum was convened by the Secretariat with the specific purpose of promoting the CHPS agenda. Papers on the CHPS process and its innovations have been presented at the annual meetings of the PAA, the American Public Health Association, the Global Health Council, the Arista 3 Nurses’ Consortium in the UK, and at two Bellagio Center conferences on the science of scaling up research, hosted by the World Health Organization. Papers have also appeared in peer-reviewed journals such as *Studies in Family Planning* and *Health Policy and Planning*.

In Year Five, the Secretariat set its sites on two additional tasks: Working with the USAID Mission to measure the impact of its Motorola communication systems pilot in advanced districts, and creating a database of private practitioners to enhance CHPS service delivery. With regards to the former, the USAID Mission asked the Secretariat to delay this activity. With regards to the latter, CHPS partners have agreed that, rather than examine a single issue, instead the Secretariat will conduct a comprehensive review of the current database system and an assessment of additional indicators and information relevant to CHPS implementation, evaluation, and service delivery, that should be incorporated. This activity will begin during Year Six.

Implementing Organization(s): Upper East Region Health Administration (CP04.05A)
Western Region Health Administration (CP04.04A)
Northern Region Health Administration (CP04.03A)
Volta Regional Health Administration (CP04.02A)
Ghana Ministry of Health (MOH) (CP04.01A)
Eastern Region Health Administration (CP03.08A)
Central Region Health Administration (CP03.04A)
Regional Institute for Population Studies (CP02.10A)
Ghana Ministry of Health (MOH) (CP02.06A)
Ghana Ministry of Health (MOH) (CP01.06A)

Activity Funding: Field Support

Contribution to Results Framework: IR 3.1

Using Nkwanta District as a Center for Excellence in Developing the Community-Based Health Planning and Services Initiative

Part of project #06613

Country/ies: Ghana
Technical Coord.: James F. Phillips, Ellie Feinglass
Period: July 2001–August 2004
Objective: To develop a Community-Based Health Planning and Services initiative (CHPS) “lead district” that can serve as a model for organizational change in the national health care program.

Activity Description:

Note: This activity comprises one part of the Population Council’s support for CHPS implementation.

By 1996 encouraging results from the Community Health and Family Planning project (CHFP) (see “The Navrongo CHFP”) began to emerge. The methodology of community dialogue and mobilization was being clarified and the beginnings of meaningful community participation in health planning and services were taking shape. Subsequent developments and research over the next four years confirmed the initial findings and outlined definitive impact, which were presented to the Ghana Ministry of Health (MOH) and other stakeholders in a series of seminars and meetings. Further deliberations on the findings at the policy level led to the acceptance of a national initiative for scaling up the CHFP experiment.

The first phase of this effort, known as the Community-Based Health Service Delivery initiative (CHSD), began in 1997 in Nkwanta District. In a pioneering move, Nkwanta modeled its service delivery strategies on the CHFP experience with spectacular results. With Nkwanta taking the lead, the CHSD became the major mechanism for resolving the national problem of accessibility to health care.

Based on this success, the MOH launched sectorwide health reforms aimed at improving access, equity, efficiency, quality, and sustainability of health and family planning services throughout Ghana. This program—named the Community-Based Health Planning and Services initiative—was launched in 1999. CHPS calls for “lead districts” to be developed in each of Ghana’s ten regions in which adaptations of the CHFP system are tried, refined, and adapted to local realities and needs. Lead districts, in turn, become demonstration areas for operational change in other districts. The Council has used its field support from USAID to award funds to Nkwanta District to develop a “lead district” strategy that can serve as a model for demonstrating and fostering operational and organizational change in the national health program.

Report of Year Five:

By the end of Year Five, the Nkwanta District has 16 CHPS zones established—eight fully functioning, three in progress with no CHO deployed, and five in the initial planning phases. The DHMT strives to complete implementation district wide in the next few years, with technical assistance provided by the CHPS-TA Program.

Between 2001 and 2004, field exchange visits were conducted with 18 implementing CHPS districts. On-site training facilities have been upgraded to allow for comprehensive practical skills training as well as classroom instruction. Follow-up visits to monitor progress have been conducted by the CHPS M&E Secretariat. This series of field exchanges will continue through funding provided by the new CHPS-TA Program.

In 2002, the Nkwanta DHMT conducted the pilot District-level Evaluation Survey (DES) and created a toolkit for using the methodology in other CHPS districts (see M&E Secretariat program report for more details). In 2004, a follow-up survey was conducted to assess whether any changes in health-seeking behavior had occurred and whether CHPS is continuing to have an impact on health indicators. The 2004 survey included a number of important modifications, including a more detailed HIV/AIDS module and a series of questions regarding migration behavior. Analysis is currently underway, and it is hoped that dissemination will occur by year's end. While PCP3 funding to Nkwanta has ended, funding from the Mellon Foundation is allowing Nkwanta to conclude this important task.

Results from the first DES demonstrate that children living in areas exposed to CHPS were 1.6 times more likely to be immunized compared with children not exposed. CHPS also had a positive impact on child health record keeping; regression analysis showed that children in CHPS areas were over two times more likely to have a health card. Within CHPS zones, 65 percent of CHPS children aged 12–24 months at the time of the survey were fully immunized. While immunization coverage is better in CHPS areas than in non-program areas, there is ample room for improvement across the district. Nkwanta has therefore focused on identifying the reasons for missed opportunities to reach children during both static and door-to-door outreach in CHPS communities. In June of 2004, staff made investigatory site visits to a number of CHPS zones, where they spoke at length with CHOs regarding the system of registering and tracking immunizations and examined their log books firsthand. This process has been instrumental in highlighting critical gaps in the system. From these visits, it became apparent that a significant proportion of children in CHPS communities were being missed altogether; many children who were immunized as newborns were subsequently lost to follow up; there was no clear, complete picture of each child's immunization status or growth over time; there was confusion among CHOs regarding upper age limits for routine immunization; and the system in place had no means of tracking administration of Vitamin A.

Based on these findings, Nkwanta has developed a new system that explicitly addresses all of the gaps identified, with a focus on keeping registers as simple as possible while improving the capacity of CHOs to immediately identify missed vaccination opportunities and/or sub optimal growth for each child in their zone. Nkwanta anticipates that this new system will have a positive impact on coverage rates in CHPS zones and, if successful, they intend to expand its use to the hospital and subdistrict clinics/health centers.

Finally, since 2002, the Nkwanta team has produced a series of newsletters entitled *Putting Success to Work*. The series complements the efforts of the NHRC to disseminate lessons learned and provide practical guidance to CHPS-implementing districts throughout Ghana. To date, Nkwanta has produced and distributed 14 issues.

Implementing Organization(s): Volta Regional Health Administration and its Nkwanta District Health Management Team (CP02.02A)

Activity Funding: Field Support

Contribution to Results Framework: IR 3.1

Understanding and Meeting the Needs of Adolescents

Program Summary

The largest generation of adolescents in world history is now making the transition to adulthood. While there have been many publications on adolescent reproductive behavior, serious gaps remain in our understanding of the adolescent experience. Researchers know little about the factors affecting adolescent reproductive outcomes; the accuracy of information provided by teenagers concerning sensitive behaviors, such as sex, pregnancy, and abortion; and the effect of different data-collection techniques on this accuracy. As a result, our ability to develop informed policy and programs that support adolescents in making a successful transition to adulthood is limited.

The Population Council's Understanding and Meeting the Needs of Adolescents program seeks to increase our understanding of the experience of adolescents in developing countries, laying the groundwork for effective policies and programs supporting these young people. Research in this program has four objectives: (1) to document patterns and trends in the incidence and timing of key events during the transition to adulthood—for example, sexual initiation, school-leaving, formal employment, marriage, and childbearing—and the interrelationships among these events; (2) to evaluate the impact of interventions designed to reduce risk-taking behaviors among adolescents; (3) to evaluate new techniques for collecting more accurate data on adolescent sexual and reproductive behavior; and (4) to assess the impact of educational and livelihood interventions on school enrollment and on the timing of marriage and childbearing. The ultimate goal of this research is to identify policies and interventions that will delay marriage and childbearing and will increase adolescents' capacity to make a successful transition to adulthood.

Research in this program is underway in Bangladesh, India, Malawi, and South Africa. In South Africa, researchers are documenting the timing, trends, and interrelationships among key events in the transition to adulthood (see above); they are also evaluating the impact of school-based life-skills instruction on adolescent behaviors (research objectives 1 and 2). In Malawi, researchers are investigating whether it is feasible to use audio computer-assisted self-interviewing (audio-CASI) to collect data on adolescents and whether this technology produces more reliable data on sexual activity and other sensitive behaviors than do traditional survey methods (research objective 3). In Bangladesh, researchers are assessing how new policies and programs affect the timing of school-leaving, marriage, and childbearing among adolescent girls (research objective 4). In India, researchers are measuring the impact of an intervention that adds vocational counseling and training to an adolescent reproductive health project through analysis of survey and case study data (research objective 4).

USAID has provided essential support for this program; indeed, funding through the Population Council Program III is necessary to complete this research. (Support from other donors supplements USAID funds.)

Patterns of Marriage and the Onset of Childbearing in Rural Bangladesh: The Impact of Large-Scale Educational and Livelihood Interventions

Part of project #05461

Country/ies: Bangladesh
Technical Coord.: Sajeda Amin
Period: October 1997–August 2004
Objective: To explore the impact of education and livelihood interventions that seek to expand opportunities for young women and delay the timing of marriage and the onset of childbearing.

Activity Description:

While Bangladesh has experienced dramatic fertility decline as a result of its successful family planning program, it continues to maintain a regime of very early marriage that has negative implications for rapid population growth. This project studies the impact of two large-scale interventions: a secondary school scholarship scheme and a pilot scheme to impart livelihood skills to adolescent girls.

The first part of the project uses data from a long-term village study to assess the impact of educational incentive schemes for children and adolescent girls. Making innovative use of previously collected data as well as data collected in 2000, the project has generated a rich set of quantitative and qualitative information. Preliminary analysis of 1995–96 data suggests that incentive schemes introduced in 1994 have resulted in rapid increases in school enrollment and may have initiated some delay in marriage for girls. Data from 2000 confirm that school enrollment increased more for girls than for boys but also indicate that the risk of dropping out of school remains strongly differentiated by gender and class. Boys in poor households are more likely to drop out than boys in nonpoor households, and all girls face similar and high risks of dropping out because of marriage. The study also finds that while school programs are successful at encouraging unmarried girls to remain in school, they do not necessarily delay girls' age at marriage. In addition, dowry payments are a menacing concern for parents, and early marriage is encouraged by perceptions that older girls will require higher dowries.

The second part of the project (2001–03) applies lessons learned from the village study to an intervention program in three rural districts—Chapainawabganj, Chittagong, and Sherpur. The goal of the intervention is to provide adolescent girls who are recent school graduates with life-skills and livelihood training. Subsequent to the training, some girls may be linked with existing savings and credit facilities. Entrepreneurship development and internship opportunities in the local communities will also be supported. UNICEF is funding the intervention, which is being carried out by BRAC and CMES, two nongovernmental organizations. To create a more supportive environment for adolescent girls, various districtwide sensitization activities are being conducted by the government, including a media campaign and training program for adolescent boys, parents, and members of the local government. The Population Council is conducting a study of the intervention.

Report of Year Five:

A critical and distinguishing element of the project and central to its success was a livelihoods approach in programming for adolescents. The interventions begin by providing space to form social networks among adolescents. It goes on to provide life-skills and livelihood skills to adolescent girls the majority of whom have schooling. Following the training, the program attempts to link them up with existing facilities for savings, credit, or employment. Entrepreneurship development and internship opportunities exist in some

areas. UNICEF is funding the interventions, which are being carried out by two NGOs, the BRAC and CMES.

The baseline survey conducted in 2001 documented important differences in the three study districts in the pattern of marriage, demands for dowry at marriage, reproductive health, and schooling of girls. In addition, the prevalence of violence against male and female adolescents was found to be high. Evidence suggests as well that parents have a strong incentive for their daughter's early marriage because dowry rises with age. On a positive note, the study highlights the important role that economic incentive schemes, in the form of secondary school scholarships for girls, have played in keeping poor children, especially adolescent girls, in school, in all three areas.

Between March and June of 2003 a midline survey was conducted in a subset of 68 of the 90 villages in the baseline. The midline survey tracked migrants who had migrated out of their own villages to areas within the district. Twenty-three percent of all girls had moved since the baseline. The baseline and follow-up surveys taken together represent a unique panel data for a cohort of girls going through important life transitions. It is also able to provide valuable information related to the interventions both in terms of the reach and selectivity of the intervention and its short-term impact. More importantly all the quantitative and qualitative data taken together provide a unique longitudinal dataset and rich material on the lives of adolescents in a changing environment. The data have been disseminated widely among development practitioners who have found the rich quantitative and qualitative data collected with careful planning to be extremely practical and valuable. Although marriage rates remain high, and drive the high out-migration rates, some marriage delays may be attributed to the interventions. The interventions are also more successful among girls who are in school and from relatively poor households in the village. The project showed that programs designed to give adolescent girls access to public spaces of their own, life-skills and reproductive health training, livelihoods training and other support to increase their earning potential can have far-reaching effects: these programs encourage increased schooling, increased income and work and delayed marriage. The qualitative data also show how programs can foster and enhance a sense of well-being among participants.

Implementing Organization(s): Population Council

Collaborating Organization(s): Women's Directorate, Government of Bangladesh

Centre for Mass Education and Sciences (CMES)

Bangladesh Rural Advancement Committee (BRAC)

UNICEF

Activity Funding: Pop Core

Contribution to Results Framework: IR 2.1

Transition to Adulthood in the Context of AIDS in South Africa

Part of project #05462

Country/ies: South Africa

Technical Coord.: Kelly Hallman

Period: February 1999–October 2004

Objective: To document patterns and trends for key events during adolescents' transitions to adulthood, and to evaluate the impact of life-skills programs on adolescent sexual behavior in South Africa.

Activity Description:

At the end of 2000, HIV prevalence among sexually active South African females ages 15–19 and 20–24 exceeded 17 and 29 percent, respectively. Adolescent childbearing levels were also high: The latest available census data (1996) show that 30 percent of females ages 20–24 gave birth by age 20. A study of adolescents in KwaZulu-Natal (KZN) Province (the province hardest hit by the AIDS epidemic) seeks to address multiple knowledge gaps about adolescent risky behavior. The main goals of the study are (1) to document patterns, trends, and relationships among key events during the transition to adulthood—including sexual initiation, school-leaving, employment patterns, marriage, and childbearing; and (2) to evaluate the impact of school-based life-skills instruction on adolescent sexual behaviors. The study is longitudinal and multilevel. A representative sample of 3,000 adolescents ages 14–22 in Durban Metro and Mtunzini districts was interviewed in 1999 and again in 2001. Data on communities were also collected. Principals from secondary schools in the study area were interviewed about life-skills instruction in their schools. Population Council Policy Research Division (PRD) staff collaborate with researchers from Horizons, MEASURE Evaluation, FOCUS, and the University of Natal-Durban on the design and implementation of the study and analysis of data. Funding from the Population Council Program III supports PRD staff and consultants. Horizons and MEASURE Evaluation (via funds from the USAID Mission in South Africa) support field costs.

Report of Year Five:

In Year Five analysis of study data continued. The effects of economic vulnerability, orphanhood, and social isolation on risky sexual behaviors were further explored. Study results indicate that the highest vulnerability to a number of HIV risk behaviors occurs among particular subgroups of females: those from low wealth households, those who are orphans, and those with few social connections. The findings are available in a new Policy Research Division Working Paper and were presented to the Population Council's Board of Trustees June 2004 meeting and at several international conferences, including the Population Association of America 2004, a Symposium on Youth Well-Being sponsored by the South African Departments of Health and Social Welfare, the Global Health Council 2004, and the XV International AIDS conference.

Progress has been made towards the development of an evidence-based, well-designed, and rigorously-evaluated intervention for young people that integrates HIV prevention with elements aimed at addressing their social isolation, economic vulnerability, and the cultural factors that prevent young people from acting upon the HIV knowledge they obtain. Efforts to collaborate with the YMCA-South Africa were not fruitful because the organization's governing body decided it should cease programming and focus instead on increasing its membership rolls. Before and since that time, we have had productive discussions with UNICEF-South Africa. This has led to a new collaboration and procurement of funding to the Policy Research Division for formative qualitative research around the new intervention elements. The program

goals continue to be the enhancement of young people's economic literacy and increasing their social networks and access to safe spaces, both at school and within the community more widely. The Population Council and UNICEF are working closely with the South Africa Department of Education to ensure that program activities respond directly to the Department's priorities and help establish "Best Practices." The Population Council and UNICEF together are seeking funding to continue the development and measure the effectiveness of these new intervention components.

Implementing Organization(s): Population Council

Collaborating Organization(s): University of Natal-Durban
Population Council/Horizons
Tulane University/MEASURE Evaluation

Activity Funding: Pop Core

Contribution to Results Framework: IR 2.1

The Reporting of Sexual Activity in Malawi

Part of project #05462

Country/ies: Malawi

Technical Coord.: Barbara Mensch

Period: July 2003–December 2004

Objective: To assess whether audio computer-assisted self-interviewing (audio-CASI) improves the reporting of sexual behavior among a sample of unmarried females ages 15–21 in Balaka, Malawi

Activity Description:

This activity is part of a much larger project conducted by the University of Pennsylvania Population Studies Center (Hans-Peter Kohler, principal investigator) with funding from the U.S. National Institutes of Health. The goal of the project is to understand, through analysis of four rounds of longitudinal data collected between 1998 and 2005, how individuals in high-HIV-risk environments cope with AIDS, manage risk, and adapt their sexual behavior. The Population Council is providing technical assistance to the project by assessing whether audio-CASI improves reporting of premarital sexual behavior. Council researchers will compare audio-CASI with face-to-face interviewing in a random sample of 500 females ages 15–21 in Balaka District, one of the three districts where the longitudinal survey is being conducted. If it is determined that audio-CASI improves reporting of premarital sexual behavior, staff at the University of Pennsylvania will then apply for additional funding to use audio-CASI to interview a larger sample in the third and final round of data collection scheduled for 2005.

Report of Year Five:

During year five, Council researchers refined the study design, designed the questionnaire, developed the ACASI software, trained the interviewers and supervised the data collection, which took place in geographically proximate areas to the panel survey being conducted by the University of Pennsylvania. In addition to answering questions about their sexual behavior, respondents provided urine samples for testing of gonorrhea and chlamydia. HIV status of study participants is also being determined by use of the OraSure® HIV ELISA test. The collection of biomarkers will allow us to investigate the strength of the association between STI/HIV status and risky sexual behavior by interview mode. Data collection was carried out from May - July 2004; data entry and cleaning are ongoing.

Implementing Organization(s): Population Council

Collaborating Organization(s): University of Pennsylvania

Activity Funding: Pop Core

Contribution to Results Framework: IR 2.1

Completion Activities and Assessment of Findings: Allahabad Project

Part of project #05461

Country/ies: India

Technical Coord.: Barbara Mensch

Period: January 2003–December 2004

Objective: To measure the impact of an intervention that adds vocational counseling and training to an adolescent reproductive health project in an urban slum in Allahabad, Uttar Pradesh, India, through analysis of survey and case study data.

Activity Description:

Note: USAID/India obligated \$200,000 USAID FY99 field support to the Expanding Contraceptive Choice (ECC) project in September 1999. With the decision to end the ECC project, the funds have been reallocated to this project.

The project investigated the feasibility and impact of adding four components to a preexisting reproductive health program (managed by CARE India) for adolescent girls in Allahabad, India: (1) counseling on savings formation and livelihoods; (2) vocational skills training; (3) assistance in opening savings accounts; and (4) follow-up support. The project uses a quasi-experimental pre- and posttest design that compares the intervention group with a control group of adolescents. The project selected peer educators from the slums and trained them in the provision of reproductive health information, communication skills, and group formation techniques. After the peer educators completed the reproductive health education series and had been trained by project staff to provide information about livelihoods and savings opportunities, they conducted group sessions about livelihoods and savings using IEC materials developed for this purpose. Nineteen short-term vocational training courses were then offered both in the slums where the girls resided and in the city of Allahabad. Concurrently with vocational skills training, counseling and assistance was provided for creating savings accounts at banks or post-offices. Evaluation activities included a baseline survey conducted from April-June, 2001, a midterm assessment that took place in April 2002, in-depth case studies conducted from February to June 2003, and an endline survey conducted from March to June 2003.

USAID funds were used for a subaward to CORT, India to complete the endline survey. Remaining funds cover in-house costs of analyzing the case studies and data from the survey.

Report of Year Five:

During year 5 Population Council researchers were involved in assessing the impact of the intervention through an analysis of the merged baseline/endline data and disseminating our findings at various conferences and workshops. Papers were presented in February at the Indian Association for the Study of Population conference, in April at the Population Association of America conference in Boston, in April at the workshop “Adolescent Girls’ Livelihoods: Building Assets for Safe, Productive Lives” in New York, in May at the “National Consultation- Young people: Towards a healthy future” in New Delhi, India and in June at the Global Health Council’s 31st Annual Conference in Washington.

The analysis of the livelihoods intervention indicates that the project had only a minimal impact on adolescent girls in the experimental slum areas of Allahabad. Nonetheless, it is noteworthy that girls in the intervention were significantly more likely to have knowledge of safe spaces, be a member of a group, score higher on the social skills index, be informed about reproductive health, and spend time on leisure

activities than the matched control respondents. No effect was found on gender role attitudes, mobility, self-esteem, work expectations, hours visiting friends, domestic chores or labor market work.

A number of factors were working against finding a substantial effect on girls' attitudes and behavior. First, only 121 of the 635 girls in the experimental slum for whom we have both baseline and endline data, participated in the intervention. Thus it is remarkable that we found any significant effects at all. Second, fielding a longitudinal survey in urban slum areas was much more problematic than originally anticipated. Even when we made concerted efforts to ensure complete coverage in the endline we still missed, or couldn't match, a large number of adolescents who had been interviewed at the baseline. Third, even if the data collection had gone smoothly, in retrospect it is clear that the intervention was of too short a duration and insufficiently intensive to have a substantial effect; the girls were not exposed to group meetings or vocational training for a long enough period of time to significantly alter their attitudes or behavior. Fourth, the intervention had only minimal contact with parents. Yet to a very large extent these girls are not in control of their lives or their futures. Thus it is important to fully engage parents in discussions of the importance of schooling, livelihoods and delayed marriage for their daughters.

Although the results were somewhat disappointing, the greatest changes were found in those measures that most closely reflected the content of the intervention. The increased knowledge of safe spaces for girls and self-identification as a group member were direct outcomes of participation in the groups that met at the home of the peer educators. Likewise, the increased social skills are a logical by-product of informal interaction within the peer groups. Finally, it is most encouraging that intervention participants showed a significant increase in reproductive health knowledge. Although some of this change may be related to better attendance in the experimental areas, there may also be some unmeasured aspect of the livelihoods component that encouraged the retention of the reproductive health information.

Implementing Organization(s): Centre for Operations Research and Training (CORT), India (CP03.02A)
Population Council

Collaborating Organization(s): CARE India

Activity Funding: Field Support

Contribution to Results Framework: IR 2.1

Transitions in Reproductive Behavior in the Developing World

Program Summary

Over the past three decades, a revolution in reproductive behavior has swept through most of the developing world. Contraceptive use, once rare, is now widespread. The average number of births per woman has fallen by half—from six or more to nearly three. These trends are welcome developments. Clearly, couples have gained more control over their reproductive lives; unfortunately, this control remains inadequate. As a result, undesired reproductive events are still widespread in developing countries, where one in five births are unwanted and more than 30 million induced abortions are performed annually.

While fertility trends have been well documented, their implications continue to be debated. Two issues are particularly relevant to policymakers: (1) prospects for continued fertility decline; and (2) the need for family planning programs to meet the ongoing demand for contraception. The Population Council's Transitions in Reproductive Behavior in the Developing World program investigates the dynamics of reproductive behavior and population trends in developing countries. Studies aim to provide new insights into the complex and controversial issues surrounding the transitions in fertility and contraceptive use in these countries, including the question of how much, and for how long, world population will continue to grow. Research findings will be documented and their implications analyzed to inform family planning programs and population policy.

USAID provides valuable support for this Council program.

Variations in Contraceptive Prevalence at the End of the Fertility Transition

Part of project #04800

Country/ies: Interregional
Technical Coord.: John Bongaarts
Period: July 2003–June 2004
Objective: To analyze contraceptive prevalence levels and trends at the end of the fertility transition.

Activity Description:

The widespread fertility declines that have occurred throughout the developing world over the past few decades have invariably been accompanied by large increases in contraceptive use. Past studies of the proximate determinants of fertility confirm that high levels of contraceptive use are the main direct cause of low fertility. However, in contemporary developing countries the levels of contraceptive use associated with a given level of fertility vary widely. For example, in countries with total fertility rates between 2 and 3 births per woman where Demographic and Health Surveys (DHS) have taken place, contraceptive prevalence ranges from a low of 39.9 percent in Colombia (1990) to 71.7 percent in Vietnam (1997). The objective of this study is to determine the causes of variation in contraceptive use associated with low fertility in countries nearing the end of their transitions. The study will analyze information from DHS on levels, trends, and socioeconomic differentials in fertility, contraceptive use, and other proximate determinants.

Final Report:

This study examined the causes of unexpected variation in contraceptive prevalence in countries that have reached the latest stage of the fertility transition (i.e. with a total fertility rate less than 3 births per woman). In these countries contraceptive prevalence among all women varies from a low of 40 percent in Colombia (1990) to 72 percent in Vietnam (1997) and among married women prevalence varies from 48 in India (1998/99) to 78 in Vietnam (2001) a range of 32 and 30 percentage points respectively. Several possible explanations were explored using data from DHS countries (ex-Soviet countries are excluded):

(1) *Expected vs. unexpected variation.* Some of the variation in prevalence in late transitional countries is due to small but real differences in fertility. To remove this expected variation from the analysis, contraceptive prevalence variation is re-measured as deviation from the regression line relating prevalence to TFR. Differences between observed and expected prevalence ranged from +5 % in Columbia (2000) to –20% in India (1998/99). After taking into account this fertility effect there is still a great deal of unexplained variance in contraceptive prevalence.

(2) *Measurement errors.* Estimates of fertility and contraceptive prevalence from DHS surveys contain inaccuracies due to sampling, design, data collection and reporting errors. In late transitional countries sampling errors are modest with typical confidence intervals of +/- 0.2 births per woman in the TFR and of +/- 2% in the prevalence rate. In well implemented surveys, non-sampling errors should also be small, but their magnitude is not easily measured. However, non-trivial deviations of prevalence from the regression line of +/- 5% should not be unusual, because errors in the TFR and prevalence can reinforce one another. Together these various errors explain a significant part of the observed variation.

(3) *Effects of other proximate variables.* Fertility is directly determined by a set of behavioral and biological variables called the proximate determinants. Contraceptive use is the most important of these, but there are

a number of others including the incidence of induced abortion, proportions married, post-partum infecundability, contraceptive effectiveness, and frequency of intercourse. Any true variation in prevalence around the expected level is caused by variation in these other proximate variables. The largest deviations were negative (i.e. observed prevalence less than expected from the regression). An analysis with the Bongaarts proximate determinants model identifies the following factors as being responsible for these negative deviations:

- South Africa (–10%): Late age at marriage
- Turkey (–8%): High abortion rate
- India (–20%): High prevalence of sterilization, long post-partum amenorrhea, downward bias in TFR, use of abortion.
- Indonesia (–10%): Effective method mix, long duration of post-partum amenorrhea.

Taken together these three explanations provide a comprehensive assessment of why prevalence varies widely among late transitional countries.

Implementing Organization(s): Population Council

Activity Funding: Pop Core

Contribution to Results Framework: IR 3.1

Urban Studies

Program Summary

Sub-Saharan Africa is currently experiencing an urban population explosion; indeed, it is now urbanizing more rapidly than any other developing region. In the coming decades, virtually all population growth in sub-Saharan Africa will be urban; yet industrialization and economic growth are not keeping pace with this trend. As a result, urban African populations increasingly inhabit informal settlements in which health conditions are poor and may be deteriorating. Nevertheless, development assistance continues to target rural Africa, while the problems associated with rapid urban growth receive inadequate attention.

In 2001 the Population Council launched the Urban Studies program to pursue research addressing the health needs of urban populations in developing countries. Two diverse urban settings in Africa were selected as the initial study sites: Nairobi, Kenya, and Ouagadougou, Burkina Faso.

In Kenya, the African Population and Health Research Centre (APHRC) launched the Nairobi Urban Health and Poverty project (NUHPP) in 1999 to address the need for systematic research and experimental interventions focusing on problems of the urban poor. The NUHPP is a program of social, survey, and experimental research designed to clarify the health problems of Nairobi's urban poor; to identify feasible interventions to improve health and livelihoods; and to test the impact of experimental interventions on health, poverty, and demographic outcomes. In Year Three of the Population Council Program III, the APHRC was issued a subaward from the Council to assess the operational elements of an NUHPP field experiment aiming to alleviate urban reproductive health problems and poverty.

In Burkina Faso, the Ouagadougou Urban Health and Equity initiative was established in the summer of 2001 to document disparities in urban health. The Council worked with this initiative to develop a proposed research protocol for two activities: (1) research on current malaria care-seeking and home management practices; and (2) a pilot intervention testing the feasibility of community-based social marketing of prepackaged chloroquine for home treatment of malaria in children. During Year Four, activities on this project commenced.

USAID has provided essential support for the Council's Urban Studies program. During Year Three USAID's Office of Population encouraged the Council to apply to USAID's Making Cities Work (MCW) Partnership Fund for support for the Nairobi project. The application was successful, and Office of Population special initiative funds were matched by the MCW Partnership Fund to support this project. The Council applied again to the MCW Partnership Fund for support of the Burkina Faso project, and again the application was successful. This time, the partnership fund matched resources from USAID's West African Regional Program (WARP) mission.

The Ouagadougou Urban Health and Equity Initiative: A Pilot Antimalarial Intervention for Disadvantaged Children

Part of project #06609

Country/ies: Burkina Faso

Technical Coord.: Julia Dayton, Mark Montgomery

Period: September 2002–December 2003

Objective: To document in two neighborhoods of Ouagadougou the feasibility of interventions to treat malaria in children; to support the development, by officials of the Regional Department of Health and the Ministry of Health, of a comprehensive strategy for urban malaria control.

Activity Description:

Note: This activity is funded by USAID's West African Regional Program and USAID/Washington's Office of Environment and Urban Programs through the Making Cities Work Partnership Fund.

The Ouagadougou Urban Health and Equity initiative is a partnership of l'Unité d'Enseignement et de Recherche en Démographie (UERD) of the University of Ouagadougou, the Population Council, Mwangaza Action, Save the Children Pays-Bas, Direction Regionale de la Santé, and the Centre National de Formation et de Recherche sur le Paludisme. UERD is one of the leading population research institutes in West Africa. With an international team of 12 full-time researchers, its expertise is recognized in three complementary fields: reproductive health, population and development strategies, and women and poverty. Mwangaza Action is a nongovernmental organization in Burkina Faso that specializes in community mobilization and the use of the participatory learning approach to health issues.

The initiative is documenting disparities in urban health and will conduct a controlled trial to measure the impact on child mortality of dual interventions against malaria in randomly selected census enumeration zones of Ouagadougou. The complementary interventions - which include using insecticide-impregnated materials and providing training on appropriate household management of malaria - have proven successful in rural settings.

This activity comprises two preparatory activities for the trial: formative research to characterize current practices for home management of and care seeking for malaria; and a pilot intervention to test the feasibility of community-based social marketing of prepackaged chloroquine for home treatment of malaria in children.

Final Report:

UERD and the National Malaria Research and Training Center (CNRF) of the Ministry of Health conducted an experiment to assess the feasibility of community-based distribution (CBD) of prepackaged therapeutic units (PTU) of chloroquine and paracetamol for home treatment of presumptive malaria. The research was conducted in two distinct and sociologically different neighborhoods of Ouagadougou-Wemtanga and Taabtenga. The intervention focused on children under age seven. A total of 47 neighborhood volunteers were trained by the District Health Team and CNRFP to provide mothers (or other household care-givers) with basic information on appropriate home management of simple malaria in their young children. For the mothers who wished to purchase it, the volunteer sold pre-packaged doses of chloroquine and paracetamol in the age-specific dosages recommended by the National Ministry of Health of Burkina Faso. UERD conducted baseline and final surveys to assess change in household practices in

care-seeking and home management of malaria in young children; follow-up interviews with a sample of clients; focus group discussions and exit interviews outside of health centers and private clinics were also used to assess community views of the intervention.

Sales records and inventory checks showed that a total of 1,779 PTUs were sold in two months (September and October 2003). End line survey results showed that in the two samples, after only two months of operations, 12 percent of children who had fevers in Wemtenga and 17 percent in Taabtenga were treated with PTUs. Two-thirds (65 percent) of the PTUs were administered during the correct amount of days (i.e., three). UERD conducted 124 PTU client interviews less than 10 days after the PTUs were purchased. Client interviews confirmed that none of the children suffered any ill effect from the PTU and that all recovered from their fever. Focus group discussion with PTU users and non-users alike indicated that there is a strong demand for home treatment of uncomplicated fevers at all ages and that the CBD strategy is acceptable despite the fact that the volunteers are not health professionals.

By providing age-specific packets of chloroquine, each with a full course of treatment, the community-based distribution of low cost anti-malarials in prepackaged age-specific therapeutic units was shown to reduce the health risks that stem from current patterns of inappropriate care. The project demonstrated that, with a minimal amount of training, community volunteers can provide quality information to local mothers and by selling at a symbolic cost (approximately 10 cents per PTU), improve the compliance of household treatments and at the same time provide a safe alternative to clinical treatment. The evaluation also validated the hypothesis that the CBD strategy was equitable - both affluent and poor households benefited from the project, and no religious or social group was excluded.

UERD and CNRFP are planning a workshop to present these results to the Ministry of Health and advocate for a comprehensive strategy for urban malaria control. The workshop should increase local understanding of appropriate treatment of simple malaria in children, drawing specific attention to differences in treatment by household wealth.

Implementing Organization(s): Teaching and Research Unit in Demography (UERD) of the University of Ouagadougou (CP03.07A)

Collaborating Organization(s): National Center for Malaria Training and Research
Regional Health Office of Ouagadougou
Population Council
Save the Children Pays-Bas
Mwangaza Action

Activity Funding: Field Support

Contribution to Results Framework: IR 3.1

USAID RESULTS FRAMEWORK

SO 1 To expand the range and optimize the use and availability of safe, effective, and acceptable technologies for the prevention of pregnancy and STIs/HIV.

Contraceptive Development

- IR 1.1 Improved and new contraceptive and reproductive health technologies developed, evaluated, and approved.
 - SR 1.1.a Improved biological knowledge base for understanding, prioritizing, and applying new or existing technologies.
 - SR 1.1.b Prototype technologies developed and tested.
 - SR 1.1.c FDA and/or host country approval obtained.
 - SR 1.1.d Private sector partnerships established.

Expanding Contraceptive Choice

- IR 1.2 Use of contraceptive and reproductive health technologies optimized and expanded.
 - SR 1.2.a Expanded knowledge of client acceptability, use dynamics, provider perspectives, and risks and benefits of technologies.
 - SR 1.2.b Products, tools, technologies, and knowledge transferred in a form that can be received, utilized, and sustained; products introduced.
 - SR 1.2.c Improved understanding of service delivery strengths and weaknesses as related to expanding technologies.
 - SR 1.2.d Effective linkages created between reproductive health technologies and development of other health technologies.

Microbicides Activities

- IR 1.3 Microbicides and microbicides/spermicides developed, evaluated, and approved.
 - SR 1.3.a Improved biological knowledge base for understanding, prioritizing, and applying new or existing technologies.
 - SR 1.3.b New and improved methodologies, tools, and technologies for management training, IEC, policy, data collection, and evaluation developed and tested.
 - SR 1.3.c Prototype technologies developed and tested.
 - SR 1.3.d FDA and/or host country approval obtained.

SO 2 Improved policy environment and increased global resources for family planning and reproductive health programs.

Mission-Funded Initiatives, Experimental Family Planning Studies in Rural Africa, Adolescents, and Transitions

- IR 2.1 Policy reform and program planning decisions at all levels are informed by timely and accurate data.
 - SR 2.1.a National and operational policies relating to family planning and reproductive health formulated, disseminated, and implemented, and barriers to service availability removed.
 - SR 2.1.b Inappropriate barriers to information and services for special populations are removed.

SO 3 Innovative service delivery strategies developed, evaluated and, where appropriate, expanded to the national level.

Mission-Funded Initiatives, Experimental Family Planning Studies in Rural Africa, Special Initiative/Urban Studies, and Special Initiative/Female Genital Cutting

IR 3.1 New and improved strategies developed, tested, and evaluated.

- SR 3.1.a Innovative service delivery strategies developed and evaluated, and existing strategies improved.
- SR 3.1.b Policy reform and program planning decisions at all levels are informed by timely and accurate data.
- SR 3.1.c Enhanced understanding of issues contributing to change of reproductive intention and behavior.

ACTIVITY GRID BY RESULTS

SO 1: To expand the range and optimize the use and availability of safe, effective, and acceptable technologies for the prevention of pregnancy and STIs/HIV.

IR 1.1: Improved and new contraceptive and reproductive health technologies developed, evaluated, and approved.

Activity	Country/ies	Status	Outcomes
Nestorone® (NES)/Ethinylestradiol (EE) Contraceptive Ring (#07902) CD	France Netherlands United States	Planning Phase 2b/3	User-controlled nonandrogenic contraceptive for women
Nestorone® (NES)/Estradiol (E2) Contraceptive Ring (#TBD) CD	United States	Inactive	User-controlled, nonandrogenic contraceptive for women
Nestorone® (NES) Implant (#07703) CD	United States	Phase 2	Long-term contraceptive method for lactating women
Nestorone® (NES), Not Method-Specific (#07600) CD	United States	Preclinical	Pharmacology, metabolism, and toxicology data on all methods delivering NES; synthesis and formulation of NES; radioimmunoassay of clinical blood samples
Jadelle® (Two-Rod Levonorgestrel Implant System) (#07702) CD	United States	Postintroduction	Extension of use-life to five years
CDB-2914 (Progesterone Receptor Modulator) (#07909) CD	Chile Dominican Republic United States	Phase 1/2; PCP3 funding discontinued	Continuous-use contraception for women
Androgen Implant (#07801) CD	Chile Germany United States	Phase 2	Hormonal contraceptive for men
Androgen, Not Method-Specific (#12400) CD	United States	Preclinical	Pharmacology, metabolism, and toxicology data on all methods delivering MENT™

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SO 1: To expand the range and optimize the use and availability of safe, effective, and acceptable technologies for the prevention of pregnancy and STIs/HIV.

IR 1.2: Use of contraceptive and reproductive health technologies optimized and expanded.

Activity	Country/ies	Status	Outcomes
Expanding Access to Coital-Dependent Methods and Dual Protection Within Youth-Centered Sexual and Reproductive Health Care Facilities (part of #03200) ECC	Ethiopia	Completed	Greater acceptability and use of coital-dependent contraceptive methods by young people; improved access to emergency contraception by young people; improved understanding of and practice of dual protection among young people
Study of Impact After the Introduction of Norplant® and Depo-Provera® in Zambia: Phase Two (#03253) ECC	Zambia	Completed	Better understanding of improvements in quality of care and impact of expanded contraceptive method introduction on quality of family planning services.
Targeting Truck Drivers for STI/HIV/AIDS Prevention, Testing, and Treatment in Foz do Iguaçu (Paraná State) and Uruguaiana (Rio Grande do Sul State) (#05827) MFI	Brazil	Ongoing	Improved access to condoms, testing, counseling, and prevention information on STI/HIV/AIDS among truck drivers crossing the border in Foz do Iguaçu; ensured access to monitoring and treatment of HIV/AIDS for truck drivers
Improving the Quality of STI/HIV/AIDS Prevention in the Brazil/Bolivia Border Region of Corumbá/Puerto Suárez (#05826) MFI	Brazil	Ongoing	Reduce STI/HIV/AIDS risk behaviors in vulnerable populations through consistent condom use; improve access to testing, counseling, and treatment; build capacity of local NGO to ensure sustainability of project
From Pilot Interventions to Regional Programs: Expanding Contraceptive Choice and Improving Quality of Care in the Copperbelt (#03262) MFI	Zambia	Ongoing	Improved service delivery mechanisms; improved method availability and acceptability; improved provider competence; increased client satisfaction; greater contraceptive choice

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SO 1: To expand the range and optimize the use and availability of safe, effective, and acceptable technologies for the prevention of pregnancy and STIs/HIV.

IR 1.3: Microbicides and microbicides/spermicides developed, evaluated, and approved.

Activity	Country/ies	Status	Outcomes
CBR: Reproductive Toxicology: Segment I and Segment II for Carraguard® (part of #08300) MICROB	United States	Completed	Evaluation of Carraguard® for potential in causing abnormal embryonic development during organogenesis and toxicity potential on maternal and embryo/fetus during the time course of test formulation dosing
CBR: Carraguard® and Placebo Production for Phase 3 Efficacy Trial (part of #08300) MICROB	United States	Ongoing	Carraguard and placebo applicators provided for Phase 3 clinical trials; stability profiles, chemical and pharmacokinetic analysis, and other evaluations carried out to satisfy FDA-requested testing
CBR: Stability Profiles for Carraguard® and Methyl Cellulose Placebo (part of #08300) MICROB	United States	Ongoing	Establish five-year stability profile for Carraguard to enhance registration as OTC product and to minimize final product pricing; establish long-term stability profile for methyl cellulose to ensure stability and usability through Phase 3 clinical trial
CBR: Preclinical Studies for Second-Generation Microbicides (part of #08300) MICROB	United States	Ongoing; USAID funding discontinued	Establish foundation for preclinical file and position PC-710 for clinical safety studies
CBR: Development of a Novel Microbicide Containing Two Anti-HIV Compounds (part of #08300) MICROB	United States	Preclinical testing necessary to gain regulatory approval for Phase I clinical study commenced	Development of safe, stable, and effective combination microbicide
CBR: Blocking DC–Virus Spread with Carrageenan-Based Agents (part of #08300) MICROB	United States	Manuscript being prepared on <i>in vitro</i> studies; animals purchased for <i>in vivo</i> studies and baseline data being gathered; study to continue with non-PCP3 funding.	The effectiveness of carrageenan-based agents in blocking virus capture and transmission by DCs <i>in vitro</i> was evaluated. The <i>in vivo</i> ability of carrageenan-based approaches to prevent vaginal transmission of virus to monkeys is currently underway with the virus challenge starting in early 2005.
CBR: Implementation of the Phase 3 Efficacy Trial of Carraguard® (part of #08300) MICROB	South Africa	Ongoing	Determine efficacy of Carraguard® in preventing HIV seroconversion in women

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SO 1: To expand the range and optimize the use and availability of safe, effective, and acceptable technologies for the prevention of pregnancy and STIs/HIV.

IR 1.3: Microbicides and microbicides/spermicides developed, evaluated, and approved.

Activity	Country/ies	Status	Outcomes
IPD: Phase 1 Safety Study of Carraguard® (PC-515) Among HIV-Positive Women and Men (#05603) MICROB	South Africa	Data collection was completed in August 2003 and data entry was completed in December 2003. Data cleaning is expected to be completed by early September 2004 at which time data analysis will commence.	Assessment of safety and acceptability of Carraguard® among HIV-positive men and women, including safety when applied directly to penis, and effect on HIV shedding in vagina
IPD: Preparation and Scale-Up for Phase 3 Efficacy Trial of Carraguard® (#05604) MICROB	South Africa	Video in English, Setswana, Xhosa, Zulu complete. Study booklet in English, Setswana, Xhosa complete; Zulu translation drafted. CAGs est. at MEDUNSA and UCT sites; appropriate community involvement at MRC site being assessed. Community consultations held.	Readiness for Phase 3 trial including increased capacity at Phase 2 sites, development of informed consent materials, transparency via CAGs and local national consultations
IPD: Implementation of the Phase 3 Efficacy Trial of Carraguard® (#05607) MICROB	South Africa	Study materials (booklet and video) completed; evaluation of the informed consent process and study materials is set to begin	Determine efficacy of Carraguard® in preventing HIV seroconversion in women
Reproductive Tract Infection Sampling Study (#05605) NT/RTI	South Africa	Completed	Assessment of performance, feasibility, and acceptability of clinic-based self-sampling; determination of prevalence of HPV subtypes in Phase 3 trial community
Home Sampling and Rapid Testing for Reproductive Tract Infections (#05608) NT/RTI	Brazil South Africa	Data collection and data management for both studies, one in Brazil and one in South Africa, which compare home-based versus clinic-based screening are ongoing; protocols for the two studies are similar to allow comparability of results.	Assessment of performance, feasibility, and acceptability of home-based and clinic-based self-sampling and rapid testing for RTIs

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SO 2: Improved policy environment and increased global resources for family planning and reproductive health programs.

IR 2.1: Policy reform and program planning decisions at all levels are informed by timely and accurate data

Activity	Country/ies	Status	Outcomes
Audio Computer-Assisted Self-Interviewing (Audio-CASI) to Assess Reporting of Sensitive Behaviors (#05609) NT/RTI	Brazil	Data collection began in April 2004 and is ongoing.	Assessment of acceptability, feasibility, and potential validity of audio-CASI compared with face-to-face interviewing in Brazil
Studies in Family Planning (#02800) CFI	United States	Completed	Two issues of Studies in Family Planning
The INTACT Network for FGM/C Research and Change (#06500) CFI	Egypt	Ongoing, now over 200 members	Expand network of researchers and provide technical training for NGO leaders working to eliminate FGC
Technical Assistance for the Implementation of the USAID Brazil Research Strategy on STI/HIV/AIDS in Brazil (#44804) MFI	Brazil	Ongoing	Development of the USAID/Brazil/MOH STI/HIV/AIDS research strategy by providing technical assistance to BEMFAM and the USAID/MOH Consortium.
Stalled Fertility Transition in Egypt (#06011) MFI	Egypt	Working on the final report	Brief report containing key findings from field survey to be conducted in late 2003 to be submitted to USAID/Cairo; analytical report to be submitted to scientific journal
Reducing Unwanted Pregnancy Among Victims of Sexual Assault: New Windows of Opportunity for Emergency Contraception (formerly Operations Research on Emergency Contraception in Zambia) (#44103) MFI	Zambia	Ongoing	Information relevant to the scaling up of emergency contraception services in Zambia provided
Patterns of Marriage and the Onset of Childbearing in Rural Bangladesh: The Impact of Large-Scale Educational and Livelihood Interventions (part of #05461) ADOL	Bangladesh	Intervention completed - final round of data collection in process	Expanded knowledge of whether, how, and to what extent interventions in areas of adolescent work and education can change marriage and childbearing patterns of girls

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SO 2: Improved policy environment and increased global resources for family planning and reproductive health programs.

IR 2.1: Policy reform and program planning decisions at all levels are informed by timely and accurate data

Activity	Country/ies	Status	Outcomes
Transition to Adulthood in the Context of AIDS in South Africa (part of #05462) ADOL	South Africa	Ongoing	Augmented knowledge of key transitions in lives of adolescents residing in volatile, high-risk environments and of impact of life-skills programs on adolescent risky sexual behavior
The Reporting of Sexual Activity in Malawi (part of #05462) ADOL	Malawi	Data collection took place from May - July 2004. Data entry is currently ongoing.	Understand whether interview context affects young women's responses to questions about premarital sex in Malawi
Completion Activities and Assessment of Findings: Allahabad Project (part of #05461) ADOL	India	Analysis of the merged baseline/endline data is ongoing. A final report is being drafted and a working paper assessing the impact of the intervention on the attitudes and behavior of adolescent girls is being revised.	Investigate feasibility of providing vocational counseling and training to adolescent girls in urban slum in India; assess impact of these opportunities on girls and their families

SO 3: Innovative service delivery strategies developed, evaluated and, where appropriate, expanded to the national level.

IR 3.1: New and improved strategies developed, tested, and evaluated.

Activity	Country/ies	Status	Outcomes
Operations Research Support for USAID/Cambodia's HIV/AIDS and Reproductive and Child Health Program (#05828) MFI	Cambodia	The activity will be completed by the end of August 2004. Currently the final version for the report is being prepared. This will be submitted to the USAID Mission and partners in July and a dissemination workshop will be held in August.	Critical programmatic issues identified and solved through application of research leading to operations research design; USAID-funded implementing agencies and local partners provided with technical assistance for evaluating service delivery strategies/interventions; improved capacity of national and local organizations to conduct research to design operations research and to use and disseminate findings
Addressing Adolescent Reproductive Health Needs: An In-Depth Study of the Gate Keepers in Uttaranchal (#44504) MFI	India	New project	Findings of formative research will contribute to OR study on reproductive health needs of adolescent boys

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SO 3: Innovative service delivery strategies developed, evaluated and, where appropriate, expanded to the national level.

IR 3.1: New and improved strategies developed, tested, and evaluated.

Activity	Country/ies	Status	Outcomes
Searching for Synergies: Dual Protection Within the Context of Provider-Dependent Contraception (#03265) MFI	Zambia	Ongoing	Develop innovative strategies for expanding use of dual protection through partner involvement and more accurate self-assessment of STI risk
Technical Assistance to the Navrongo Community Health and Family Planning Project and the Community-Based Health Planning and Services Initiative (part of #04700) XFP	Ghana	Ongoing	Technical expertise provided to Ghanaian partners to conduct experimental health and family planning research and develop monitoring and evaluation systems for nationwide expansion of experimental research; technical expertise provided to disseminate results from experiment and expansion
The Navrongo Community Health and Family Planning Project (part of #04700) XFP	Ghana	Continuing end-of-project phase in which treatment and control areas are reversed, which will determine extent to which variance is explained by cultural and social characteristics versus actual program effect when CHFP services are scaled up	Service activities and community organization and mobilization demonstrated to have impact on primary health care and family planning services use and effectiveness; fertility and mortality reduced
The Navrongo Demographic Surveillance System: Demographic Surveillance for the Community Health and Family Planning Project (part of #04700) XFP	Ghana	Ended	Proper assessment of demographic impact of CHFP experiment
A Community-Informed Experiment in Preventing Female Genital Cutting Among the Kassena-Nankana of Northern Ghana (part of #04700) XFP	Ghana	Scale up of intervention activities in comparison area underway; dissemination plan for end of project ongoing	Reduction of FGC demonstrated via community organization and action in setting where practice has been nearly universal
Disseminating Lessons Learned from the Navrongo Community Health and Family Planning Project (part of #06613) XFP	Ghana	Final 4 issues of What Works being produced. A final compendium volume is being produced	Findings from CHFP disseminated to health providers nationwide; efforts to replicate CHFP nationwide informed; information on experiment disseminated to international research community

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SO 3: Innovative service delivery strategies developed, evaluated and, where appropriate, expanded to the national level.

IR 3.1: New and improved strategies developed, tested, and evaluated.

Activity	Country/ies	Status	Outcomes
Establishing a Community-Based Health Planning and Services Initiative Monitoring and Evaluation (M&E) Secretariat and Creating an Appropriate M&E Strategy (part of #06613) XFP	Ghana	Monitoring & reporting system activities ongoing; latest rounds of strategic assessments & demographic impact studies being evaluated; small grants program ongoing in 5 districts	Impact of nationwide expansion and replication of CHFP informed by development and maintenance of systems to accurately monitor and evaluate CHPS activity
Using Nkwanta District as a Center for Excellence in Developing the Community-Based Health Planning and Services Initiative (part of #06613) XFP	Ghana	Completed	Nationwide expansion and replication of CHFP informed by counterpart training in CHPS process and sharing technologies; lead district provides guidance to other districts within region for CHPS implementation
Variations in Contraceptive Prevalence at the End of the Fertility Transition (part of #04800) TRANS	Interregional	Completed	Improved understanding of relationship between contraceptive prevalence and fertility at end of transition
The Ouagadougou Urban Health and Equity Initiative: A Pilot Antimalarial Intervention for Disadvantaged Children (part of #06609) URBAN	Burkina Faso	Completed	Malaria prevention and treatment strategies in urban areas better understood; health policy informed

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ACTIVITY GRID BY COUNTRY**Bangladesh**

Activity	Result	Status	Outcomes
Patterns of Marriage and the Onset of Childbearing in Rural Bangladesh: The Impact of Large-Scale Educational and Livelihood Interventions (part of #05461) ADOL	IR 2.1	Intervention completed - final round of data collection in process	Expanded knowledge of whether, how, and to what extent interventions in areas of adolescent work and education can change marriage and childbearing patterns of girls

Brazil

Activity	Result	Status	Outcomes
Home Sampling and Rapid Testing for Reproductive Tract Infections (#05608) NT/RTI	IR 1.3	Data collection and data management for both studies, one in Brazil and one in South Africa, which compare home-based versus clinic-based screening are ongoing; protocols for the two studies are similar to allow comparability of results.	Assessment of performance, feasibility, and acceptability of home-based and clinic-based self-sampling and rapid testing for RTIs
Audio Computer-Assisted Self-Interviewing (Audio-CASI) to Assess Reporting of Sensitive Behaviors (#05609) NT/RTI	IR 2.1	Data collection began in April 2004 and is ongoing.	Assessment of acceptability, feasibility, and potential validity of audio-CASI compared with face-to-face interviewing in Brazil
Targeting Truck Drivers for STI/HIV/AIDS Prevention, Testing, and Treatment in Foz do Iguaçu (Paraná State) and Uruguaiana (Rio Grande do Sul State) (#05827) MFI	IR 1.2	Ongoing	Improved access to condoms, testing, counseling, and prevention information on STI/HIV/AIDS among truck drivers crossing the border in Foz do Iguaçu; ensured access to monitoring and treatment of HIV/AIDS for truck drivers
Improving the Quality of STI/HIV/AIDS Prevention in the Brazil/Bolivia Border Region of Corumbá/Puerto Suárez (#05826) MFI	IR 1.2	Ongoing	Reduce STI/HIV/AIDS risk behaviors in vulnerable populations through consistent condom use; improve access to testing, counseling, and treatment; build capacity of local NGO to ensure sustainability of project
Technical Assistance for the Implementation of the USAID Brazil Research Strategy on STI/HIV/AIDS in Brazil (#44804) MFI	IR 2.1	Ongoing	Development of the USAID/Brazil/MOH STI/HIV/AIDS research strategy by providing technical assistance to BEMFAM and the USAID/MOH Consortium.

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Burkina Faso

Activity	Result	Status	Outcomes
The Ouagadougou Urban Health and Equity Initiative: A Pilot Antimalarial Intervention for Disadvantaged Children (part of #06609) URBAN	IR 3.1	Completed	Malaria prevention and treatment strategies in urban areas better understood; health policy informed

Cambodia

Activity	Result	Status	Outcomes
Operations Research Support for USAID/Cambodia's HIV/AIDS and Reproductive and Child Health Program (#05828) MFI	IR 3.1	The activity will be completed by the end of August 2004. Currently the final version for the report is being prepared. This will be submitted to the USAID Mission and partners in July and a dissemination workshop will be held in August.	Critical programmatic issues identified and solved through application of research leading to operations research design; USAID-funded implementing agencies and local partners provided with technical assistance for evaluating service delivery strategies/interventions; improved capacity of national and local organizations to conduct research to design operations research and to use and disseminate findings

Chile

Activity	Result	Status	Outcomes
CDB-2914 (Progesterone Receptor Modulator) (#07909) CD	IR 1.1	Phase 1/2; PCP3 funding discontinued	Continuous-use contraception for women
Androgen Implant (#07801) CD	IR 1.1	Phase 2	Hormonal contraceptive for men

Dominican Republic

Activity	Result	Status	Outcomes
CDB-2914 (Progesterone Receptor Modulator) (#07909) CD	IR 1.1	Phase 1/2; PCP3 funding discontinued	Continuous-use contraception for women

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Egypt

Activity	Result	Status	Outcomes
The INTACT Network for FGM/C Research and Change (#06500) CFI	IR 2.1	Ongoing, now over 200 members	Expand network of researchers and provide technical training for NGO leaders working to eliminate FGC
Stalled Fertility Transition in Egypt (#06011) MFI	IR 2.1	Working on the final report	Brief report containing key findings from field survey to be conducted in late 2003 to be submitted to USAID/Cairo; analytical report to be submitted to scientific journal

Ethiopia

Activity	Result	Status	Outcomes
Expanding Access to Coital-Dependent Methods and Dual Protection Within Youth-Centered Sexual and Reproductive Health Care Facilities (part of #03200) ECC	IR 1.2	Completed	Greater acceptability and use of coital-dependent contraceptive methods by young people; improved access to emergency contraception by young people; improved understanding of and practice of dual protection among young people

France

Activity	Result	Status	Outcomes
Nestorone® (NES)/Ethinylestradiol (EE) Contraceptive Ring (#07902) CD	IR 1.1	Planning Phase 2b/3	User-controlled nonandrogenic contraceptive for women

Germany

Activity	Result	Status	Outcomes
Androgen Implant (#07801) CD	IR 1.1	Phase 2	Hormonal contraceptive for men

Ghana

Activity	Result	Status	Outcomes
Technical Assistance to the Navrongo Community Health and Family Planning Project and the Community-Based Health Planning and Services Initiative (part of #04700) XFP	IR 3.1	Ongoing	Technical expertise provided to Ghanaian partners to conduct experimental health and family planning research and develop monitoring and evaluation systems for nationwide expansion of experimental research; technical expertise provided to disseminate results from experiment and expansion

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Ghana

Activity	Result	Status	Outcomes
The Navrongo Community Health and Family Planning Project (part of #04700) XFP	IR 3.1	Continuing end-of-project phase in which treatment and control areas are reversed, which will determine extent to which variance is explained by cultural and social characteristics versus actual program effect when CHFP services are scaled up	Service activities and community organization and mobilization demonstrated to have impact on primary health care and family planning services use and effectiveness; fertility and mortality reduced
The Navrongo Demographic Surveillance System: Demographic Surveillance for the Community Health and Family Planning Project (part of #04700) XFP	IR 3.1	Ended	Proper assessment of demographic impact of CHFP experiment
A Community-Informed Experiment in Preventing Female Genital Cutting Among the Kassena-Nankana of Northern Ghana (part of #04700) XFP	IR 3.1	Scale up of intervention activities in comparison area underway; dissemination plan for end of project ongoing	Reduction of FGC demonstrated via community organization and action in setting where practice has been nearly universal
Disseminating Lessons Learned from the Navrongo Community Health and Family Planning Project (part of #06613) XFP	IR 3.1	Final 4 issues of What Works being produced. A final compendium volume is being produced	Findings from CHFP disseminated to health providers nationwide; efforts to replicate CHFP nationwide informed; information on experiment disseminated to international research community
Establishing a Community-Based Health Planning and Services Initiative Monitoring and Evaluation (M&E) Secretariat and Creating an Appropriate M&E Strategy (part of #06613) XFP	IR 3.1	Monitoring & reporting system activities ongoing; latest rounds of strategic assessments & demographic impact studies being evaluated; small grants program ongoing in 5 districts	Impact of nationwide expansion and replication of CHFP informed by development and maintenance of systems to accurately monitor and evaluate CHPS activity
Using Nkwanta District as a Center for Excellence in Developing the Community-Based Health Planning and Services Initiative (part of #06613) XFP	IR 3.1	Completed	Nationwide expansion and replication of CHFP informed by counterpart training in CHPS process and sharing technologies; lead district provides guidance to other districts within region for CHPS implementation

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India

Activity	Result	Status	Outcomes
Addressing Adolescent Reproductive Health Needs: An In-Depth Study of the Gate Keepers in Uttaranchal (#44504) MFI	IR 3.1	New project	Findings of formative research will contribute to OR study on reproductive health needs of adolescent boys
Completion Activities and Assessment of Findings: Allahabad Project (part of #05461) ADOL	IR 2.1	Analysis of the merged baseline/endline data is ongoing. A final report is being drafted and a working paper assessing the impact of the intervention on the attitudes and behavior of adolescent girls is being revised.	Investigate feasibility of providing vocational counseling and training to adolescent girls in urban slum in India; assess impact of these opportunities on girls and their families

Interregional

Activity	Result	Status	Outcomes
Variations in Contraceptive Prevalence at the End of the Fertility Transition (part of #04800) TRANS	IR 3.1	Completed	Improved understanding of relationship between contraceptive prevalence and fertility at end of transition

Malawi

Activity	Result	Status	Outcomes
The Reporting of Sexual Activity in Malawi (part of #05462) ADOL	IR 2.1	Data collection took place from May - July 2004. Data entry is currently ongoing.	Understand whether interview context affects young women's responses to questions about premarital sex in Malawi

Netherlands

Activity	Result	Status	Outcomes
Nestorone® (NES)/Ethinylestradiol (EE) Contraceptive Ring (#07902) CD	IR 1.1	Planning Phase 2b/3	User-controlled nonandrogenic contraceptive for women

South Africa

Activity	Result	Status	Outcomes
CBR: Implementation of the Phase 3 Efficacy Trial of Carraguard® (part of #08300) MICROB	IR 1.3	Ongoing	Determine efficacy of Carraguard® in preventing HIV seroconversion in women

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South Africa

Activity	Result	Status	Outcomes
IPD: Phase 1 Safety Study of Carraguard® (PC-515) Among HIV-Positive Women and Men (#05603) MICROB	IR 1.3	Data collection was completed in August 2003 and data entry was completed in December 2003. Data cleaning is expected to be completed by early September 2004 at which time data analysis will commence.	Assessment of safety and acceptability of Carraguard® among HIV-positive men and women, including safety when applied directly to penis, and effect on HIV shedding in vagina
IPD: Preparation and Scale-Up for Phase 3 Efficacy Trial of Carraguard® (#05604) MICROB	IR 1.3	Video in English, Setswana, Xhosa, Zulu complete. Study booklet in English, Setswana, Xhosa complete; Zulu translation drafted. CAGs est. at MEDUNSA and UCT sites; appropriate community involvement at MRC site being assessed. Community consultations held.	Readiness for Phase 3 trial including increased capacity at Phase 2 sites, development of informed consent materials, transparency via CAGs and local national consultations
IPD: Implementation of the Phase 3 Efficacy Trial of Carraguard® (#05607) MICROB	IR 1.3	Study materials (booklet and video) completed; evaluation of the informed consent process and study materials is set to begin	Determine efficacy of Carraguard® in preventing HIV seroconversion in women
Reproductive Tract Infection Sampling Study (#05605) NT/RTI	IR 1.3	Completed	Assessment of performance, feasibility, and acceptability of clinic-based self-sampling; determination of prevalence of HPV subtypes in Phase 3 trial community
Home Sampling and Rapid Testing for Reproductive Tract Infections (#05608) NT/RTI	IR 1.3	Data collection and data management for both studies, one in Brazil and one in South Africa, which compare home-based versus clinic-based screening are ongoing; protocols for the two studies are similar to allow comparability of results.	Assessment of performance, feasibility, and acceptability of home-based and clinic-based self-sampling and rapid testing for RTIs
Transition to Adulthood in the Context of AIDS in South Africa (part of #05462) ADOL	IR 2.1	Ongoing	Augmented knowledge of key transitions in lives of adolescents residing in volatile, high-risk environments and of impact of life-skills programs on adolescent risky sexual behavior

United States

Activity	Result	Status	Outcomes
Nestorone® (NES)/Ethinylestradiol (EE) Contraceptive Ring (#07902) CD	IR 1.1	Planning Phase 2b/3	User-controlled nonandrogenic contraceptive for women

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United States

Activity	Result	Status	Outcomes
Nestorone® (NES)/Estradiol (E2) Contraceptive Ring (#TBD) CD	IR 1.1	Inactive	User-controlled, nonandrogenic contraceptive for women
Nestorone® (NES) Implant (#07703) CD	IR 1.1	Phase 2	Long-term contraceptive method for lactating women
Nestorone® (NES), Not Method-Specific (#07600) CD	IR 1.1	Preclinical	Pharmacology, metabolism, and toxicology data on all methods delivering NES; synthesis and formulation of NES; radioimmunoassay of clinical blood samples
Jadelle® (Two-Rod Levonorgestrel Implant System) (#07702) CD	IR 1.1	Postintroduction	Extension of use-life to five years
CDB-2914 (Progesterone Receptor Modulator) (#07909) CD	IR 1.1	Phase 1/2; PCP3 funding discontinued	Continuous-use contraception for women
Androgen Implant (#07801) CD	IR 1.1	Phase 2	Hormonal contraceptive for men
Androgen, Not Method-Specific (#12400) CD	IR 1.1	Preclinical	Pharmacology, metabolism, and toxicology data on all methods delivering MENT™
CBR: Reproductive Toxicology: Segment I and Segment II for Carraguard® (part of #08300) MICROB	IR 1.3	Completed	Evaluation of Carraguard® for potential in causing abnormal embryonic development during organogenesis and toxicity potential on maternal and embryo/fetus during the time course of test formulation dosing
CBR: Carraguard® and Placebo Production for Phase 3 Efficacy Trial (part of #08300) MICROB	IR 1.3	Ongoing	Carraguard and placebo applicators provided for Phase 3 clinical trials; stability profiles, chemical and pharmacokinetic analysis, and other evaluations carried out to satisfy FDA-requested testing
CBR: Stability Profiles for Carraguard® and Methyl Cellulose Placebo (part of #08300) MICROB	IR 1.3	Ongoing	Establish five-year stability profile for Carraguard to enhance registration as OTC product and to minimize final product pricing; establish long-term stability profile for methyl cellulose to ensure stability and usability through Phase 3 clinical trial

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United States

Activity	Result	Status	Outcomes
CBR: Preclinical Studies for Second-Generation Microbicides (part of #08300) MICROB	IR 1.3	Ongoing; USAID funding discontinued	Establish foundation for preclinical file and position PC-710 for clinical safety studies
CBR: Development of a Novel Microbicide Containing Two Anti-HIV Compounds (part of #08300) MICROB	IR 1.3	Preclinical testing necessary to gain regulatory approval for Phase I clinical study commenced	Development of safe, stable, and effective combination microbicide
CBR: Blocking DC–Virus Spread with Carrageenan-Based Agents (part of #08300) MICROB	IR 1.3	Manuscript being prepared on in vitro studies; animals purchased for <i>in vivo</i> studies and baseline data being gathered; study to continue with non-PCP3 funding.	The effectiveness of carrageenan-based agents in blocking virus capture and transmission by DCs in vitro was evaluated. The <i>in vivo</i> ability of carrageenan-based approaches to prevent vaginal transmission of virus to monkeys is currently underway with the virus challenge starting in early 2005.
Studies in Family Planning (#02800) CFI	IR 2.1	Completed	Two issues of Studies in Family Planning

Zambia

Activity	Result	Status	Outcomes
Study of Impact After the Introduction of Norplant® and Depo-Provera® in Zambia: Phase Two (#03253) ECC	IR 1.2	Completed	Better understanding of improvements in quality of care and impact of expanded contraceptive method introduction on quality of family planning services.
From Pilot Interventions to Regional Programs: Expanding Contraceptive Choice and Improving Quality of Care in the Copperbelt (#03262) MFI	IR 1.2	Ongoing	Improved service delivery mechanisms; improved method availability and acceptability; improved provider competence; increased client satisfaction; greater contraceptive choice
Searching for Synergies: Dual Protection Within the Context of Provider-Dependent Contraception (#03265) MFI	IR 3.1	Ongoing	Develop innovative strategies for expanding use of dual protection through partner involvement and more accurate self-assessment of STI risk

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Zambia

Activity	Result	Status	Outcomes
Reducing Unwanted Pregnancy Among Victims of Sexual Assault: New Windows of Opportunity for Emergency Contraception (formerly Operations Research on Emergency Contraception in Zambia) (#44103) MFI	IR 2.1	Ongoing	Information relevant to the scaling up of emergency contraception services in Zambia provided

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PUBLICATIONS AND OTHER WRITTEN WORKS

Publications

Contraceptive Development

Anderson, Richard A., A. Michael Wallace, Naveed Sattar, Narender Kumar, and Kalyan Sundaram. 2003. "Evidence for tissue selectivity of the synthetic androgen 7 α -methyl-19-nortestosterone in hypogonadal men," *Journal of Clinical Endocrinology and Metabolism* 88(6): 2784–2793.

Sitruk-Ware, Régine, Margaret Small, Narender Kumar, Yun-yen Tsong, Kalyan Sundaram, and Theodore M. Jackanicz. 2003. "Nestorone[®]: Clinical applications for contraception and HRT," *Steroids* 68(10–13): 907–913.

von Eckardstein, Sigrid, Gabriela Noe, Vivian Brache, Eberhard Nieschlag, Horacio B. Croxatto, Francisco Alvarez, Alfred J. Moo-Young, Irving Sivin, Narender Kumar, Margaret Small, and Kalyan Sundaram. 2003. "A clinical trial of 7 α -methyl-19-nortestosterone implants for possible use as a long-acting contraceptive for men," *Journal of Clinical Endocrinology and Metabolism* 88(11): 5232–5239.

Microbicides Program

Clacherty, Glynis and Barbara Friedland, with Alana de Kock and Mabitso Marumo. 2004. "Testing Carraguard: What you need to know," study booklet. Johannesburg: Population Council (also available in Setswana, Xhosa, and Zulu).

Friedland, Barbara (exec. prod.). 2004. "Testing Carraguard: What you need to know," video. Auckland Park, South Africa: Pandamonium Productions (also available in Setswana and Xhosa).

Hu, Qinxue, Ines Frank, Vennansha Williams, John J. Santos, Patricia Watts, George E. Griffin, John P. Moore, Melissa J. Pope, and Robin J. Shattock. 2004. "Blockade of attachment and fusion receptors inhibits HIV-1 infection of human cervical tissue," *Journal of Experimental Medicine* 199(8): 1065–1075.

Turville, Stuart G., John J. Santos, Ines Frank, Paul U. Cameron, John Wilkinson, Monica Miranda-Saksena, Joanne Dable, Hella Stössel, Nikolaus Romani, Michael Piatak, Jr., Jeffrey D. Lifson, Melissa Pope, and Anthony L. Cunningham. 2004. "Immunodeficiency virus uptake, turnover and 2-phase transfer in human dendritic cells," *Blood* 103(6): 2170–2179.

Core-Funded Initiatives

International Network to Analyze, Communicate and Transform the Campaign Against FGC/FGM/FC. n.d. INTACT brochure. Cairo: Palm Press.

International Network to Analyze, Communicate and Transform the Campaign Against FGC/FGM/FC. n.d. INTACT Web site, www.intact-network.net.

Studies in Family Planning 34(3) and 34(4)

Mission-Funded Initiatives

Noletto, Dario (ed.). 2003. "A aids nas fronteiras do Brasil: diagnóstico estratégico da situação da epidemia de aids e doenças sexualmente transmissíveis nas fronteiras do Brasil" [AIDS in the borders of Brazil: Strategic diagnosis of the situation of the AIDS epidemic and sexually transmitted illnesses in the borders of Brazil], report. Brasília: Ministério da Saúde/Programa Nacional de DST e Aids.

Skibiak, John, Humphres Evelia, Edmond Bagde, and Kelly Blanchard (eds.). 2004. *ECafrique Bulletin: African Forum on Emergency Contraception*, vol. 2/1, January–March.

———. 2004. *ECafrique Bulletin: African Forum on Emergency Contraception*, vol. 2/2, May.

Experimental Family Planning Studies in Rural Africa

Jackson, Elizabeth F., Patricia Akweongo, Evelyn Sakeah, Abraham Hodgson, Rofina Asuru, and James F. Phillips. 2003. "Inconsistent reporting of female genital cutting status in northern Ghana: Explanatory factors and analytical consequences," *Studies in Family Planning* 34(3): 200–210.

———. 2003. "Women's denial of having experienced female genital cutting in northern Ghana: Explanatory factors and consequences for analysis of survey data," *Policy Research Division Working Paper* no. 178. New York: Population Council.

Navrongo Health Research Centre. 2002. "District 88888 calling!" *What Works? What Fails? Findings from the Navrongo Community Health and Family Planning Project 2*(26). Navrongo, Ghana: Ministry of Health. (*Published in Year Four.*)

———. 2002. "Health by the boatload," *What Works? What Fails? Findings from the Navrongo Community Health and Family Planning Project 2*(27). Navrongo, Ghana: Ministry of Health. (*Published in Year Four.*)

———. 2002. “This is our CHPS,” *What Works? What Fails? Findings from the Navrongo Community Health and Family Planning Project 2*(28). Navrongo, Ghana: Ministry of Health. (Published in Year Four.)

———. 2002. “Who’s behind the scenes?” *What Works? What Fails? Findings from the Navrongo Community Health and Family Planning Project 2*(29). Navrongo, Ghana: Ministry of Health. (Published in Year Four.)

———. 2002. “‘Trust’ as health insurance,” *What Works? What Fails? Findings from the Navrongo Community Health and Family Planning Project 2*(30). Navrongo, Ghana: Ministry of Health. (Published in Year Four.)

———. 2003. “Who’s in charge here?” *What Works? What Fails? Findings from the Navrongo Community Health and Family Planning Project 3*(4). Navrongo, Ghana: Ministry of Health.

———. 2003. “Gates without computers,” *What Works? What Fails? Findings from the Navrongo Community Health and Family Planning Project 3*(5). Navrongo, Ghana: Ministry of Health.

———. 2003. “Health, the people’s choice,” *What Works? What Fails? Findings from the Navrongo Community Health and Family Planning Project 3*(6). Navrongo, Ghana: Ministry of Health.

———. 2003. “Before the beginning,” *What Works? What Fails? Findings from the Navrongo Community Health and Family Planning Project 3*(7). Navrongo, Ghana: Ministry of Health.

———. 2003. “Sai’s insights: So far, how far?” *What Works? What Fails? Findings from the Navrongo Community Health and Family Planning Project 3*(8). Navrongo, Ghana: Ministry of Health.

———. 2003. “Sai of relief,” *What Works? What Fails? Findings from the Navrongo Community Health and Family Planning Project 3*(9). Navrongo, Ghana: Ministry of Health.

———. 2003. “Do you speak mathematics?” *What Works? What Fails? Findings from the Navrongo Community Health and Family Planning Project 3*(10). Navrongo, Ghana: Ministry of Health.

———. 2003. “Health cannot wait,” *What Works? What Fails? Findings from the Navrongo Community Health and Family Planning Project 3*(11). Navrongo, Ghana: Ministry of Health.

———. 2003. “The board of trustees,” *What Works? What Fails? Findings from the Navrongo Community Health and Family Planning Project 3*(12). Navrongo, Ghana: Ministry of Health.

———. 2003. “Need, the mother of innovation,” *What Works? What Fails? Findings from the Navrongo Community Health and Family Planning Project 3*(13). Navrongo, Ghana: Ministry of Health.

- . 2003. “Sam’s sums,” *What Works? What Fails? Findings from the Navrongo Community Health and Family Planning Project 3*(14). Navrongo, Ghana: Ministry of Health.
- . 2003. “A pio’s opinion,” *What Works? What Fails? Findings from the Navrongo Community Health and Family Planning Project 3*(15). Navrongo, Ghana: Ministry of Health.
- . 2003. “Of paramount importance,” *What Works? What Fails? Findings from the Navrongo Community Health and Family Planning Project 3*(16). Navrongo, Ghana: Ministry of Health.
- . 2003. “Leading the leaders,” *What Works? What Fails? Findings from the Navrongo Community Health and Family Planning Project 3*(17). Navrongo, Ghana: Ministry of Health.
- . 2003. “Child survival: What worked and what failed?” *What Works? What Fails? Findings from the Navrongo Community Health and Family Planning Project 3*(18). Navrongo, Ghana: Ministry of Health.
- . 2003. “Once upon a time,” *What Works? What Fails? Findings from the Navrongo Community Health and Family Planning Project 3*(19). Navrongo, Ghana: Ministry of Health.
- . 2003. “Central viewpoint,” *What Works? What Fails? Findings from the Navrongo Community Health and Family Planning Project 3*(20). Navrongo, Ghana: Ministry of Health.
- . 2003. “Double trouble,” *What Works? What Fails? Findings from the Navrongo Community Health and Family Planning Project 3*(21). Navrongo, Ghana: Ministry of Health.
- . 2004. “Even the blind can see,” *What Works? What Fails? Findings from the Navrongo Community Health and Family Planning Project 4*(1). Navrongo, Ghana: Ministry of Health.
- . 2004. “Bring Cairo to Kayoro,” *What Works? What Fails? Findings from the Navrongo Community Health and Family Planning Project 4*(2). Navrongo, Ghana: Ministry of Health.
- . 2004. “Dying for health,” *What Works? What Fails? Findings from the Navrongo Community Health and Family Planning Project 4*(3). Navrongo, Ghana: Ministry of Health.
- . 2004. “A matter of life and death,” *What Works? What Fails? Findings from the Navrongo Community Health and Family Planning Project 4*(4). Navrongo, Ghana: Ministry of Health.
- . 2004. “HIV: Sounding the alarm!” *What Works? What Fails? Findings from the Navrongo Community Health and Family Planning Project 4*(5). Navrongo, Ghana: Ministry of Health.
- . 2004. “The right road to Bamako,” *What Works? What Fails? Findings from the Navrongo Community Health and Family Planning Project 4*(6). Navrongo, Ghana: Ministry of Health.

———. 2004. “What’s on a soothsayer’s mind?” *What Works? What Fails? Findings from the Navrongo Community Health and Family Planning Project* 4(7). Navrongo, Ghana: Ministry of Health.

———. 2004. “Women speak, men listen,” *What Works? What Fails? Findings from the Navrongo Community Health and Family Planning Project* 4(8). Navrongo, Ghana: Ministry of Health.

———. 2004. “Fertile grounds for results,” *What Works? What Fails? Findings from the Navrongo Community Health and Family Planning Project* 4(9). Navrongo, Ghana: Ministry of Health.

———. 2004. “Bicycle with a flat tyre,” *What Works? What Fails? Findings from the Navrongo Community Health and Family Planning Project* 4(10). Navrongo, Ghana: Ministry of Health.

———. 2004. “With a 25-hour duty call . . .” *What Works? What Fails? Findings from the Navrongo Community Health and Family Planning Project* 4(11). Navrongo, Ghana: Ministry of Health.

———. 2004. “The dynamics of change,” *What Works? What Fails? Findings from the Navrongo Community Health and Family Planning Project* 4(12). Navrongo, Ghana: Ministry of Health.

———. 2004. “Communities leading communities,” *What Works? What Fails? Findings from the Navrongo Community Health and Family Planning Project* 4(13). Navrongo, Ghana: Ministry of Health.

———. 2004. “Paga without borders,” *What Works? What Fails? Findings from the Navrongo Community Health and Family Planning Project* 4(14). Navrongo, Ghana: Ministry of Health.

———. 2004. “When what works fails,” *What Works? What Fails? Findings from the Navrongo Community Health and Family Planning Project* 4(15). Navrongo, Ghana: Ministry of Health.

———. 2004. “Frankly speaking . . .” *What Works? What Fails? Findings from the Navrongo Community Health and Family Planning Project* 4(16). Navrongo, Ghana: Ministry of Health.

———. 2004. “Where the CHiPs fall,” *What Works? What Fails? Findings from the Navrongo Community Health and Family Planning Project* 4(17). Navrongo, Ghana: Ministry of Health.

———. 2004. “Interaction and contraception,” *What Works? What Fails? Findings from the Navrongo Community Health and Family Planning Project* 4(18). Navrongo, Ghana: Ministry of Health.

———. 2004. “Who nurses the nurse?” *What Works? What Fails? Findings from the Navrongo Community Health and Family Planning Project 4*(19). Navrongo, Ghana: Ministry of Health.

———. 2004. “Who’s putting success to work?” *What Works? What Fails? Findings from the Navrongo Community Health and Family Planning Project 4*(20). Navrongo, Ghana: Ministry of Health.

———. 2004. “What’s in the basket?” *What Works? What Fails? Findings from the Navrongo Community Health and Family Planning Project 4*(21). Navrongo, Ghana: Ministry of Health.

———. 2004. “First among equals!” *What Works? What Fails? Findings from the Navrongo Community Health and Family Planning Project 4*(22). Navrongo, Ghana: Ministry of Health.

———. 2004. “Making what works work,” *What Works? What Fails? Findings from the Navrongo Community Health and Family Planning Project 4*(23). Navrongo, Ghana: Ministry of Health.

———. 2004. “Looking beyond what works,” *What Works? What Fails? Findings from the Navrongo Community Health and Family Planning Project 4*(24). Navrongo, Ghana: Ministry of Health.

Nyonator, Frank K., J. Koku Awoonor-Williams, James F. Phillips, Tanya C. Jones, and Robert A. Miller. 2003. “The Ghana Community-based Health Planning and Services initiative: Fostering evidence-based organizational change and development in a resource-constrained setting,” *Policy Research Division Working Paper* no. 180. New York: Population Council.

Phillips, James F. 2003. “Demographic surveillance systems,” in Paul Demeny and Geoffrey McNicoll (eds.), *Encyclopedia of Population*, vol. 1. New York: Macmillan Reference USA, pp. 204–206.

Phillips, James F., Tanya C. Jones, Frank K. Nyonator, and Shruti Ravikumar. 2003. “Evidence-based development of health and family planning programs in Bangladesh and Ghana,” *Policy Research Division Working Paper* no. 175. New York: Population Council.

Understanding and Meeting the Needs of Adolescents

Amin, Sajeda. Forthcoming. “Child rights in Bangladesh,” in Dina Siddiqi (ed.), *Human Rights in Bangladesh: 2004*. Dhaka: Ain o Shalish Kendra.

Hallman, Kelly. 2004. “Socioeconomic disadvantage and unsafe sexual behaviors among young women and men in South Africa,” *Policy Research Division Working Paper* no. 190. New York: Population Council.

Hallman, Kelly and Monica Grant. 2004. "Poverty, educational attainment, and livelihoods: How well do young people fare in KwaZulu Natal, South Africa?" *Horizons Research Summary*. Washington, DC: Population Council.

Hewett, Paul C., Barbara S. Mensch, and Annabel S. Erulkar. 2003. "Consistency in the reporting of sexual behavior among adolescent girls in Kenya: A comparison of interviewing methods," *Policy Research Division Working Paper* no. 182. New York: Population Council.

Lloyd, Cynthia B., Sahar El-Tawila, Wesley H. Clark, and Barbara S. Mensch. 2003. "The impact of educational quality on school exit in Egypt," *Comparative Education Review* 47(4): 444–467.

Quisumbing, Agnes and Kelly Hallman. 2003. "Marriage in transition: Evidence on age, education, and assets from six developing countries," *Policy Research Division Working Paper* no. 183. New York: Population Council. (Commissioned by the National Academy of Sciences Panel on Transitions to Adulthood in Developing Countries.)

Transitions in Reproductive Behavior in the Developing World

Bongaarts, John. 2003. "Completing the fertility transition in the developing world: The role of educational differences and fertility preferences," *Population Studies* 57(3): 321–336.

Assessing the Impact of Improved Quality of Care on Women's Ability to Reduce Unintended Childbearing

(These publications were developed during Year Five based on data collected in previous funding years.)

Galdos, Susana, Lucella Campbell, Patricia Mohammed, Debbie Rogow, Saumya RamaRao, Ali Muhammad Mir, and Nicole Haberland. 2004. "Linking reproductive health to social power: Community health workers in Belize and Pakistan," *Quality/Calidad/Qualité* no. 15. New York: Population Council.

RamaRao, Saumya and Raji Mohanam. 2003. "The quality of family planning programs: Concepts, measurements, interventions, and effects," *Studies in Family Planning* 34(4): 227–248.

Sanogo, Diouratié, Saumya RamaRao, Heidi Jones, Penda N'Diaye, Bineta M'bow, and Cheikh Bamba Diop. 2003. "Improving quality of care and use of contraceptives in Senegal," *African Journal of Reproductive Health* 7(2): 57–73.

Other Written Works

Contraceptive Development

Population Council Center for Biomedical Research. 2003. "CDB-2914 vaginal ring," response to U.S. Food and Drug Administration (FDA) request for Investigational New Drug (IND) information, 30 July.

———. 2003. "Jadelle[®]," request for NDA information related to Venezuela registration for Schering Oy presented to the FDA, 25 August.

———. 2003. "Jadelle[®]," electronic file on serum LNG levels for New Drug Application (NDA) presented to the FDA, 3 September.

———. 2003. "Lambda-kappa-carrageenan," annual report on IND application presented to the FDA, 19 September.

———. 2003. "MENT Ac implant," IND safety report presented to the FDA, 27 August.

———. 2003. "MENT Ac implant," response to FDA request for IND information, 16 October.

———. 2004. "Carraguard/levonorgestrel vaginal gel," initial IND submission presented to the FDA, 26 March.

———. 2004. "Carraguard/levonorgestrel vaginal gel," response to FDA request for IND information, 11 May.

———. 2004. "CDB-2914 vaginal ring," annual report on IND application and new IND protocol submission presented to the FDA, 8 March.

———. 2004. "Jadelle[®]," Supplements 004 and 005 for NDA presented to the FDA, 6 February.

———. 2004. "Jadelle[®]," response to FDA request for NDA information on Supplement 004, 18 February.

———. 2004. "Jadelle[®]," response to FDA request for NDA information on Supplement 004, 1 June.

———. 2004. "Jadelle[®]," response to FDA request for NDA information on Supplement 005, 7 June.

———. 2004. "Jadelle[®]," annual report on New Drug Application (NDA) presented to the FDA, 14 June.

———. 2004. “Lambda-kappa-carrageenan,” new IND protocol submission presented to the FDA, 2 March.

———. 2004. “Nestorone[®] implant,” annual report on IND application presented to the FDA, 25 February.

———. 2004. “Nestorone[®] intrauterine delivery system,” final IND report and request to inactivate the IND presented to the FDA, 26 May.

———. 2004. “Nestorone[®] transdermal gel,” annual report on IND application presented to the FDA, 28 May.

———. 2004. “Norplant[®],” commitment on analytical procedures for NDA presented to the FDA, 26 April.

———. 2004. “Norplant[®],” annual report on NDA presented to the FDA, 14 June.

Microbicides Program

Braunstein, S., N. Morar, S. Gumede, G. Ndlovu, B. Friedland, T. Ferguson, G. Ramjee, and J. van de Wijgert. 2004. “Acceptability of Carraguard[®] among HIV-infected women and men in a safety trial in South Africa,” poster presentation at Microbicides 2004, London, 28–31 March.

Friedland, B., M. Marumo, and E. Maleka. 2003. “Burdens and benefits in a Phase II trial of Carraguard in South Africa: A case study,” oral presentation at the International Consultation on Ethical Issues in the Clinical Testing of Microbicides, Washington, DC, 23–24 October.

Friedland, B., P. Marumo, A. de Kock, S. Skoler, V. Ngcozela, C. Monedi, E. McGrory, and J. van de Wijgert. 2004. “Development of a recruitment video for a Phase 3 trial of Carraguard[®],” oral presentation at Microbicides 2004, London, 28–31 March.

Molete, D., A. Pistorius, M. Rathlagana, and B. Friedland. 2004. “Community participation in a Ga-Rankuwa/Soshanguve Phase III Carraguard trial[®],” poster presentation at Microbicides 2004, London, 28–31 March.

Morar, N., S. Braunstein, H. Jones, M. Moodley, J. Aboobaker, M. Ndaba, G. Ndlovu, J. van de Wijgert, and G. Ramjee. 2004. “Safety of Carraguard[®] among HIV-positive women and men in South Africa,” oral presentation at Microbicides 2004, London, 28–31 March.

Morcock, D.R., J.A. Thomas, T.D. Gagliardi, R.J. Gorelick, J.D. Roser, E.N. Chertova, J.W. Bess, Jr., D.E. Ott, I. Frank, M. Pope, J.D. Lifson, L.E. Henderson, and B.J. Crise. 2004. “Elimination of retroviral infectivity by *N*-ethylmaleimide with preservation of functional envelope glycoproteins,” *Journal of Virology*, in press.

Pistorius, A., M. Marumo, M. Moleté, and M. Ratlhagana. 2003. "Community involvement in the Ga-Rankuwa and Soshanguve microbicide trials of Carraguard® (Population Council)," oral presentation at the Dialogue on Community Involvement in Microbicide Trials in Southern Africa, Johannesburg, 28–30 July.

Rathlagana, M., A. Pistorius, D. Moleté, B. Friedland, and S. Skoler. 2004. "Partner involvement in a Phase III Carraguard® trial," poster presentation at Microbicides 2004, London, 28–31 March.

van de Wijgert, J. and H. Jones. 2003. "Benefits and burdens in microbicide trials: Real-life experiences," oral presentation at the International Consultation on Ethical Issues in the Clinical Testing of Microbicides, Washington, DC, 23–24 October.

New Technologies and Strategies for RTI Interventions

Allan, B.R., L. Altini, J. van de Wijgert, H. Jones, N. Coetzee, and A.L. Williamson. 2003. "Prevalence and typing of human papillomavirus from matched cervical and vaginal samples from South African women," oral presentation at the 15th Biennial Congress of the International Society for Sexually Transmitted Diseases Research, Ottawa, Canada, 27–30 July.

Altini, L., H. Jones, J. van de Wijgert, T. Young, A. de Kock, A. Hoosen, and N. Coetzee. 2003. "Validity, acceptability, and feasibility of self-sampling for reproductive tract infections in South African women," oral presentation at the 15th Biennial Congress of the International Society for Sexually Transmitted Diseases Research, Ottawa, Canada, 27–30 July.

———. 2004. "Validity and feasibility of self-sampling for reproductive tract infections in South Africa," poster presentation at Microbicides 2004, London, 28–31 March.

de Kock, A., L. Altini, H. Jones, J. van de Wijgert, T. Young, and N. Coetzee. 2003. "Understanding the acceptability of self-sampling methods for reproductive tract infections in South African women," oral presentation at the 1st South African AIDS Conference, Durban, 3–6 August.

de Kock, A., L. Altini, J. van de Wijgert, H. Jones, T. Young, and N. Coetzee. 2004. "Understanding the acceptability of self-sampling methods for reproductive tract infections in South African women," poster presentation at Microbicides 2004, London, 28–31 March.
Luppi, Carla Gianna, Sheri Lippman, Heidi Jones, Ruta Loreto Oliveira, Adriana Pinho, Maria Amélia Veras, Christiane Jesus, Diana Careaga, Janneke van de Wijgert, Manoel Ribeiro, and H. Caiaffa. 2004. "Uso de auto-coleta e teste rápido para o diagnóstico de infecções sexualmente transmissíveis em mulheres" [Use of auto-collection and rapid tests for the diagnosis of sexually transmitted infections in women], poster presentation at the VI Congresso Brasileiro de Epidemiologia, Recife, Brazil, 19–23 June.

Luppi, Carla Gianna, Sheri Lippman, Heidi Jones, Adriana Pinho, Maria Amélia Veras, Diana Careaga, Ruta Loreto Oliveira, Christiane Jesus, Manoel Ribeiro, Paul Hewett, and Barbara

Mensch. 2004. “O uso de entrevistas informatizadas (ACASI) para medir o comportamento sexual e o risco de infecções sexualmente transmissíveis em mulheres” [The use of informal interviews (ACASI) to measure the sexual behavior and the risk of sexually transmitted infections in women], poster presentation at the VI Congresso Brasileiro de Epidemiologia, Recife, Brazil, 19–23 June.

“Projeto Saber Saúde: Instruções para a auto-coleta de material vaginal” [Project Know Your Health: Instructions for self-collection of vaginal material], pamphlet for “Home sampling and rapid testing for reproductive tract infections.” São Paulo: Population Council, 2004.

“Você está sendo convidada a participar do Projeto Saber Saúde” [You are being invited to participate in Project Know Your Health], pamphlet for “Home sampling and rapid testing for reproductive tract infections.” São Paulo: Population Council, 2004.

Young, T., L. Altini, H. Jones, and J. van de Wijgert. 2003. “An evaluation of the quality of RTI case management within a research setting,” poster presentation at the 15th Biennial Congress of the International Society for Sexually Transmitted Diseases Research, Ottawa, Canada, 27–30 July.

Core-Funded Initiatives

Bur, Mona and Nafissatou Diop. 2004. “Questionnaire for groups and individuals working on FGC: Survey and findings from Burkina Faso, Egypt, Guinea, and Senegal,” PowerPoint presentation and report presented at Population Reference Bureau, Washington, DC, 4 May.

Mission-Funded Initiatives

Bortolanza, E.C., A. Donini, M.I. França, C. Pereira, S. Lippman, and M. Chinaglia. 2004. “Construindo espaços coletivos para a expressão e o diálogo: fortalecendo a comunidade de profissionais do sexo para a prevenção de DST/HIV/Aids em Corumbá, MS” [Constructing collective spaces for expression and dialogue: Fortifying the community of sex professionals for the prevention of HIV/AIDS/STDs in Corumbá, MS], poster and paper presented at the Congresso Brasileiro de DST/Aids, Recife, Brazil, 28 August–1 September.

“Caminhoneiro, sim. Prevenindo, também” [I’m a trucker. I’m a preventer as well], pamphlet and booklet for “Targeting truck drivers for STI/HIV/AIDS prevention, testing, and treatment in Foz do Iguaçu (Paraná State) and Uruguaiiana (Rio Grande do Sul State).” São Paulo: Population Council, 2003 (also available in Spanish).

“Caminhoneiro, sim. Prevenindo, também. Use sempre camisinha” [I’m a trucker. I’m a preventer as well. Always use condoms], poster and sticker for “Targeting truck drivers for STI/HIV/AIDS prevention, testing, and treatment in Foz do Iguaçu (Paraná State) and Uruguaiiana (Rio Grande do Sul State).” São Paulo: Population Council, 2003.

Chinaglia, Magda, Sheri Lippman, Julie Pulerwitz, M.S. Setúbal, Christine Ogura, and Juan Díaz. 2004. "Tailoring STI/HIV programs to the needs of mobile populations: The 'Saúde na Estrada' project for truck drivers at the tri-country border in Foz do Iguaçu, Brazil," poster presented at the XV International AIDS Conference, Bangkok, 11–16 July.

Donini, A., Sheri Lippman, E. Bortolanza, C. Laudari, C. Simonetti, C. Pereira, and D. Kerrigan. 2004. "Constructing collective spaces for expression and dialogue: Strengthening the community of sex workers for STI/HIV prevention in Corumbá, MS," presentation at the XV International AIDS Conference, Bangkok, 11–16 July.

Lippman, Sheri, A. Donini, J.M. Faria, Magda Chinaglia, M.S. Kasar, L. Laudari, R. Domingues, and Juan Díaz. 2004. "Building bridges for partnerships through project 'Encontros': Bringing government, NGOs, civil society, and the sex worker community together in a multidisciplinary STI/HIV prevention project with sex workers in Corumbá, MS," poster presentation at the XV International AIDS Conference, Bangkok, 11–16 July.

Lippman, Sheri, Julie Pulerwitz, Arthur Reingold, Magda Chinaglia, Christina Ogura, A. Hubbard, and Johannes van Dam. 2004. "Mobility and sexual partnerships of truck drivers in southern Brazil," presentation at the XV International AIDS Conference, Bangkok, 11–16 July.

Pulerwitz, Julie, Sheri Lippman, M.S. Setúbal, Magda Chinaglia, C. Takae-Ogura, Johannes van Dam, and Juan Díaz. 2004. "Measuring and addressing HIV/AIDS stigma among truckers in Brazil," presentation at the XV International AIDS Conference, Bangkok, 11–16 July.

Republic of Zambia Central Board of Health. "From pilot interventions to regional programs: Expanding contraceptive choice and improving quality of care in the Copperbelt," narrative report for the reporting period May–October 2003, Population Council award #102.16A.

"Vamos construir juntos um espaço de diálogo" [We will build a dialogue space together], pamphlet for "Targeting truck drivers for STI/HIV/AIDS prevention, testing, and treatment in Foz do Iguaçu (Paraná State) and Uruguaiana (Rio Grande do Sul State)." São Paulo: Population Council, 2004.

Experimental Family Planning Studies in Rural Africa

Adongo, Philip B., Rofina Asuru, Abraham Hodgson, and Ellie Feinglass. 2004. "Addressing men's concerns about reproductive health services in a rural community mobilization program," paper presented at the annual meeting of the Population Association of America, Boston, 1–3 April.

Akazili, James et al. 2003. "Key findings from the 2002 panel survey report," CHFP Project Documentation Note no. 48. Navrongo, Ghana: Navrongo Health Research Centre.

Akweongo, Patricia, Elizabeth F. Jackson, and Reshma Naik. 2004. "The preliminary impact of a broad-based intervention to decrease the incidence of female genital mutilation: Lessons learned

from the Navrongo FGC experiment,” paper presented at the Global Health Conference, Washington, DC, 1–4 June.

Antwi, Patricia, Frank Nyonator, Tanya C. Jones, Emmanuel Kuffour, and Emerson Arhia. 2004. “Impact of CHPS on maternal health in the Abura Asebu Kwamankese District in Ghana,” paper presented at the annual meeting of the Population Association of America, Boston, 1–3 April.

Avogo, Winfred, Cornelius Debpuur, and Philomena Nyarko. 2003. “Social networks and contraceptive use in the Kassena-Nankana District, Ghana,” poster presented at the annual meeting of the American Public Health Association, San Francisco, 15–19 November.

Awoonor-Williams, John K., Ellie S. Feinglass, Rachel Tobey, and Maya N. Vaughan-Smith. 2004. “From experiment to policy: Scaling up the CHPS initiative in rural Ghana,” paper presented at the annual meeting of the Population Association of America, Boston, 1–3 April.

Awoonor-Williams, John K., James F. Phillips, Tanya C. Jones, and Frank K. Nyonator. 2003. “Catalyzing large-scale organizational change by replicating an experimental approach to health system development in Nkwanta District, Ghana,” paper presented at the annual meeting of the American Public Health Association, San Francisco, 15–19 November.

Baiden, Frank, Abraham Hodgson, John Williams, Cornelius Debpuur, James F. Phillips, and Fred Binka. 2004. “Changing epidemiology of HIV/AIDS in Ghana: Any link to the civil war in neighboring la Côte d’Ivoire?” paper presented at the annual meeting of the Population Association of America, Boston, 1–3 April.

Binka, Fred, Ayaga A. Bawah, and Mian B. Hossain. 2004. “The role of childhood mortality in fertility transition in a rural Sahelian district of northern Ghana,” paper presented at the annual meeting of the Population Association of America, Boston, 1–3 April.

Debpuur, Cornelius. 2004. “The contribution of community-based programs on reproductive change in Ghana,” presentation at the Symposium on Reproductive Change in Ghana: Recent Patterns, Future Prospects, University of Ghana/Legon, 23–24 June.

Debpuur, Cornelius, Winfred Avogo, and James F. Phillips. 2004. “Fertility intentions and child survival in a rural Ghanaian community,” poster presented at the annual meeting of the Population Association of America, Boston, 1–3 April.

Doctor, Henry et al. 2004. “Kassena-Nankana District Demographic and Health Survey, 2003,” CHFP Project Documentation Note no. 49. Navrongo, Ghana: Navrongo Health Research Centre.

Naik, Reshma, Elizabeth F. Jackson, Patricia Akweongo, and James F. Phillips. 2004. “Inconsistent reporting of female genital cutting status among adolescent girls in a longitudinal intervention study in northern Ghana,” paper presented at the annual meeting of the Population Association of America, Boston, 1–3 April.

Nyarko, Philomena Efua. 2004. "A research design to evaluate the CHPS initiative at the regional level," unpublished report from the CHPS M&E Secretariat and the Regional Institute of Population Studies, University of Ghana/Legon, presented to the Population Council.

Nyonator, Frank K. et al. 2004. "CHPS Monitoring and Evaluation Secretariat report on the status of implementation of the Community-based Health Planning and Services initiative, July 1–December 31, 2003," unpublished report presented to the Government of Ghana, USAID, and the Population Council.

———. 2004. "CHPS Monitoring and Evaluation Secretariat report on the status of implementation of the Community-based Health Planning and Services initiative, January 1–March 31, 2004," unpublished report presented to the Government of Ghana, USAID, and the Population Council.

Sory, Elias K., Tanya C. Jones, James F. Phillips, and Frank K. Nyonator. 2003. "Grassroots mobilization to accelerate the introduction of community-based health service delivery in Ghana: Strategic assessment of the CHPS program in the Central Region of Ghana," paper presented at the annual meeting of the American Public Health Association, San Francisco, 15–19 November.

Understanding and Meeting the Needs of Adolescents

Diers, Judith and Kelly Hallman. 2003. "Evidence-based programming to address the social isolation and economic vulnerability of adolescent girls and boys in the context of HIV," presentation at UNICEF Headquarters, New York, July.

Grant, Monica. 2004. "The effect of integrating livelihoods into reproductive health programs in India," presentation at the Global Health Conference, Washington, DC, 1–4 June.

Hallman, Kelly. 2004. "Adolescent livelihood assets and gendered HIV risks in South Africa," presentation at the Population Council meeting on adolescent girls' livelihoods, Building Assets for Safe, Productive Lives, New York, April.

———. 2004. "Socio-economic context of young people in KwaZulu-Natal," presentation at South Africa Youth Symposium, Going from Context, to Services and Behavior Change, Johannesburg, South Africa, March.

———. 2004. "Transitions to livelihoods in KwaZulu-Natal, South Africa," presentation at the Population Council meeting on adolescent girls' livelihoods, Building Assets for Safe, Productive Lives, New York, April.

Hallman, Kelly and Judith Diers. 2004. "Social isolation and economic vulnerability: Adolescent HIV and pregnancy risk factors in South Africa," presentation at the annual meeting of the Population Association of America, Boston, 1–3 April.

———. 2004 “Social isolation and economic vulnerability: Adolescent HIV risk factors in South Africa,” presentation at the Global Health Conference, Washington, DC, 1–4 June.

Hallman, Kelly, Judith Diers, Nick Swan, Lewis Ndhlovu, and Cynthia Lloyd. 2004. “Evidence-based research to inform programs for young people,” presentation at UNICEF Stakeholders’ Retreat on Strategies to Reduce Gender-Based Violence, KwaZulu Natal, South Africa, May.

Hewett, Paul C., Barbara S. Mensch, and Annabel S. Erulkar. 2003. “Consistency in the reporting of sexual behavior among adolescent girls in Kenya: A comparison of interviewing methods,” paper presented at the Workshop on Measurement of Sexual Behaviour in the Era of HIV/AIDS, London School of Hygiene and Tropical Medicine, London, September.

Mensch, Barbara S., Monica Grant, Mary Sebastian, Paul Hewett, and Dale Huntington. 2004. “The effect of a livelihoods intervention in an urban slum in India: Does vocational counseling and training alter the attitudes and behavior of adolescent girls?” paper presented at the annual meeting of the Population Association of America, Boston, 1–3 April.

Sebastian, Mary and Monica Grant. 2004. “Influence of a livelihoods intervention on mobility, peer networking and decisionmaking among adolescent girls in an urban slum setting in India,” paper presented at the Population Council meeting on adolescent girls’ livelihoods, Building Assets for Safe, Productive Lives, New York, April.

Suran, Luciana and Sajeda Amin. 2004. “Does dowry make life better for brides? A test of the bequest theory of dowry in rural Bangladesh,” paper presented at the annual meeting of the Population Association of America, Boston, 1–3 April.

Assessing the Impact of Improved Quality of Care on Women’s Ability to Reduce Unintended Childbearing

(These publications were developed during Year Five based on data collected in previous funding years.)

Kim, Jacqueline. 2003. “Quality of care and family planning in the Philippines, Senegal, and Pakistan,” presentation at MAQ/CPI Meeting, Washington, DC, 29 October.

RamaRao, Saumya. 2004. “Contraceptive use and continuation results,” Presentation at MAQ/CPI Workshop, Washington, DC, 22 January.

Sathar, Zeba, Anrudh Jain, Saumya RamaRao, Minhaj ul Haque, and Jacqueline Kim. In press. “Making a client centered approach to reproductive health succeed in a Pakistani setting,” *Studies in Family Planning*.